

MIMEDX GROUP, INC.

Form 10-K

March 31, 2011

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-K**

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the Fiscal Year Ended December 31, 2010**  
**Commission file number 0-52491**  
**MIMEDX GROUP, INC.**  
(Exact name of registrant as specified in its charter)

**Florida** **26-2792552**  
(State or other jurisdiction of incorporation) (I.R.S. Employer Identification Number)

**811 Livingston Court, Suite B** **30067**  
**Marietta, GA** (Zip Code)  
(Address of principal executive offices)

**(678) 384-6720**  
Registrant's telephone number, including area code  
Securities registered pursuant to Section 12(b) of the Act: None  
Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value \$0.001 per share  
(Title of class)

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229,405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Smaller reporting company

Non-accelerated filer o  
(Do not check if a  
smaller reporting  
company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  
o No

The aggregate market value of Common Stock held by non-affiliates on June 30, 2010, based upon the last sale price of the shares as reported on the OTC Bulletin Board on such date, was approximately \$50,174,049.

There were 71,201,349 shares of Common Stock outstanding as of March 15, 2011.

**Documents Incorporated by Reference**

Portions of the proxy statement relating to the 2011 annual meeting of shareholders, to be filed within 120 days after the end of the fiscal year to which this report relates, are incorporated by reference in Part III of this Report.

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**PART I**

This Form 10-K and certain information incorporated herein by reference contain forward-looking statements and information within the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. This information includes assumptions made by, and information currently available to management, including statements regarding future economic performance and financial condition, liquidity and capital resources, acceptance of the Company's products by the market, and management's plans and objectives. In addition, certain statements included in this and our future filings with the Securities and Exchange Commission (SEC), in press releases, and in oral and written statements made by us or with our approval, which are not statements of historical fact, are forward-looking statements. Words such as may, could, should, would, believe, expect, anticipate, estimate, intend, seeks, plan, will, should, and other words or expressions of similar meaning are intended by us to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are found at various places throughout this report and in the documents incorporated herein by reference. These statements are based on our current expectations about future events or results and information that is currently available to us, involve assumptions, risks, and uncertainties, and speak only as of the date on which such statements are made.

Our actual results may differ materially from those expressed or implied in these forward-looking statements. Factors that may cause such a difference, include, but are not limited to those discussed in Part I, Item 1A, Risk Factors, below. Except as expressly required by the federal securities laws, we undertake no obligation to update any such factors, or to publicly announce the results of, or changes to any of the forward-looking statements contained herein to reflect future events, developments, changed circumstances, or for any other reason.

As used herein, the terms the Company, we, our and us refer to MiMedx Group, Inc., a Florida corporation (formerly Alynx, Co.), and its consolidated subsidiaries as a combined entity, except where it is clear that the terms mean only MiMedx Group, Inc.

**Item 1. Business**

**Overview**

MiMedx Group, Inc. (MiMedx Group) is an integrated developer, manufacturer and marketer of patent-protected biomaterial-based products. MiMedx Group is emerging from a development-focused start-up company into a fully integrated operating company with the expertise to capitalize on its science and technology and the capacity to generate sales growth and profitability.

Repair, don't replace is the mantra of the MiMedx Group biochemists, engineers, and designers who are developing today's biomaterial-based solutions for patients and physicians. Market research shows the first desire of patients ranging from active baby-boomers and weekend warriors to high-school and professional athletes is to augment repair when possible, rather than replace traumatized, but otherwise healthy tissues and structures. Clinical research has proven that biomaterials can be used to achieve augmentation and repair.

**Recent Events**

On January 5, 2011, the Company acquired all of the outstanding equity interests in Surgical Biologics, LLC, for an aggregate of \$500,000 in cash, \$1,200,000 in notes payable, 5,200,000 shares of MiMedx Common Stock, \$183,000 in debt, and certain additional contingent considerations. This strategic acquisition brings together market leading know-how in amnion tissue processing technology with a global distribution network uniquely positioned to rapidly exploit significant market opportunities across multiple surgical indications.

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Surgical Biologics, ( SB ), is located in Kennesaw, Georgia. Surgical Biologics develops bioimplants processed from human amniotic membrane that can be used for a wide range of surgical indications including ocular surface repair, gum repair, wound care, burns, and many other types of surgery that require the repair of a patient's integumental (native) tissue. SB is focused on developing technologically innovative bioimplants that offer the surgeon a variety of clinical options; allowing for greater flexibility in treatment, as well as improved surgical results.

Surgical Biologics currently distributes tissue in several different membrane subsegments, such as ocular, dental, spine and wound care. The wound care and tissue management market in the U.S. is currently valued at approximately \$7.4B, while the regenerative dental market accounts for \$232M. The Millennium Research Group has projected the anti-adhesion market to reach an estimated \$500M in 2012, whereas experts agree that the ocular market is valued at approximately \$100M. Each market's sub-segment has unique competitors, products and distribution methods.

Amniotic membrane, as processed by SB, has unique bio-active properties that offer benefits that most competitive products cannot offer. SB's tissues provide anti-inflammatory, anti-angiogenesis, anti-scarring and barrier properties as well as enhanced healing at the surgical site.

Surgical Biologics has developed a specialized process for the processing of its products. This patent pending process, named Purion, consists of unique methods which maximize yield, while minimizing manufacturing costs. The Purion process was engineered to create an implant that is optimized for ease of use while providing the patient with the maximum assurance of safety. Surgical Biologics currently has seven patents pending that have been filed with the United States Patent Office. The patent filings consist of the intellectual property used to process tissues and/or apply the tissues in a unique manner in surgery.

In addition to the existing implants, SB is in the final stages of development of new offerings for the wound care, burn, general surgery, gynecology and ENT surgery markets. Thus far, amniotic tissues for these uses show great promise, and the Company has begun limited commercial distribution for such purposes. The wound care tissue, which is undergoing a multi-center clinical evaluation, also has shown particular promise; and the Company believes that this tissue has the potential to surpass all other products in commercial distribution. SB continues to research new opportunities for amniotic tissue, and currently has several additional offerings in the first stages of conceptualization.

**Our Strategy**

The Company's initial business strategy was to identify and acquire innovative new medical products and technologies, focused primarily on the musculoskeletal market, as well as novel medical instrumentation and surgical techniques. We subsequently refined our strategy to focus on our proprietary biomaterial technologies that can be transformed into unique medical devices that fill an unmet or underserved clinical need. Our HydroFix hydrogel technology and our CollaFix collagen fiber technology are proprietary platforms that can serve as the basis for medical devices in various orthopedic and orthobiologic applications, such as spine, sports medicine, and trauma. We also have identified multiple product opportunities in general surgery, drug delivery, wound management and cardiac markets, among others.

Our plan is to focus our internal commercialization efforts relative to our HydroFix™ and CollaFix™ materials on orthopedics and orthobiologic applications. As appropriate, we may partner with large, established companies in the general surgery, drug delivery, wound management, cardiac and other markets. Initial conversations with respect to such external relationships have been initiated, but they will take time to develop.

We have organized an advisory panel of leading physicians to provide insight into our primary fields of interest for new products and technology, as well as guidance and advice with respect to ongoing product development programs. Our core focus is on near-term opportunities for each of our technologies, advancing them through the regulatory process, establishing reliable and cost-effective manufacturing, and establishing an effective distribution system.

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**History of MiMedx Group, Inc.**

MiMedx Group, Inc. originally was formed as a Utah corporation on July 30, 1985, under the name Leibra, Inc. We later changed domicile, through a merger, to Nevada, and subsequently changed our name to Alynx, Co. We had several additional name changes in connection with various business acquisitions, all of which were discontinued or rescinded. We were an inactive shell corporation for 10 years or more, seeking to acquire an interest in a business with long-term growth potential. On March 6, 2007, Alynx, Co. filed a registration statement with the SEC on Form 10-SB to register its common stock under the Securities Exchange Act of 1934.

In a merger consummated on February 8, 2008, Alynx, Co. acquired MiMedx, Inc., a Florida-based, privately-held, development-stage medical device company ( MiMedx ) founded by Steve Gorlin, currently Vice Chairman of MiMedx Group, Inc. MiMedx's assets included three development units focused on the development of medical devices based on their respective patented and proprietary technologies. MiMedx's primary development unit was focused on the development of products for the repair of soft tissue, such as tendons, ligaments and cartilage, using a collagen fiber-based platform predicated on certain cross linking technology, which was licensed from Shriners Hospital for Children and University of South Florida Research Foundation in January 2007. The assets of MiMedx also included 100% of the membership interests in SpineMedica, LLC ( SpineMedica ), a development-stage company focused on Orthopedic-Spine biomaterial technologies using a poly-vinyl alcohol ( PVA ) based hydrogel that its predecessor, SpineMedica Corp., licensed from SaluMedica, LLC for applications related to the spine in August 2005, and for applications related to the hand (excluding the wrist) and rotator cuff in August 2007. In October 2009, the license agreement was amended to exclude applications related to the hand. Additionally, MiMedx's assets included certain intellectual property related to implants for use in fracture fixation in the upper extremities, which we referred to as the Level Orthopedics assets. These assets had been contributed to, or developed on behalf of, MiMedx pursuant to a consulting agreement it had entered into in September 2007, with Thomas J. Graham, M.D., a leading hand surgeon.

On March 31, 2008, Alynx, Co. merged into MiMedx Group, Inc., a Florida corporation and wholly-owned subsidiary that had been formed on February 28, 2008, for purposes of the merger. MiMedx Group, Inc. was the surviving corporation in the merger. Also on March 31, 2008, MiMedx entered into a license with SaluMedica, LLC, for the PVA-based hydrogel biomaterial for applications as a surgical sheet outside of the spine.

To assist the Company in transitioning from a development stage company to an operating company, effective February 24, 2009, the Company's Board of Directors appointed Parker H. Pete Petit to serve as the Company's Chairman of the Board, President and Chief Executive Officer. Mr. Petit has over 30 years' experience in the healthcare products and services markets, and a track record of having successfully nurtured several companies from the development stage to industry leadership. In September 2009, Mr. Petit recruited another experienced medical device executive, William C. Taylor, to become the Company's President and Chief Operating Officer. Mr. Taylor has over 20 years' of medical device design, development, and manufacturing experience.

On April 20, 2009, we received clearance from the U.S. Food and Drug Administration (the FDA ) to market our Paradís Vaso Shield device, indicated for use as a cover for vessels following anterior vertebral surgery. In October 2009, we divested our Level Orthopedics assets in order to focus exclusively on biomaterials, and also relinquished the SaluMedica license for the hydrogel application in the hand.

Prior to the 4<sup>th</sup> quarter of 2009, the Company explored business strategies through our three development units, MiMedx, SpineMedica and Level Orthopedics. After the sale of the Level assets and a thorough review of the strategic direction of the Company, management made the decision in late 2009 to consolidate the organizational structure. Instead of independent development teams and manufacturing locations, we now have integrated development teams and all manufacturing has been consolidated into one site. Our Tampa, Florida location focuses on early stage product and process development. Our Marietta, Georgia location houses our corporate headquarters, our development and sales teams and all manufacturing and distribution operations.



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In December 2009 we made the decision to simplify our corporate and technology branding in order to build a stronger brand identity. Our new branding strategy is to focus on MiMedx Group, Inc. as the corporate brand identity and to brand each of our technologies, rather than each product embodying our technologies. Our PVA Hydrogel technology is now called HydroFix and our collagen fiber technology is now called CollaFix. During 2010, we transitioned the name of our current product from Paradis Vaso Shield to HydroFix Vaso Shield.

In February 2010, the Company received the CE Mark for its HydroFix™ Spine Shield device, which is indicated for use in certain locations along the anterior spine as a plane of dissection during revision surgery.

In June 2010, the Company received 510(k) clearance for additional thicknesses and sizes of its HydroFix™ Vaso Shield.

In December 2010, the Company received the CE Mark for its HydroFix™ Spine Shield device as a post surgical adhesion barrier.

In December 2010, the Company signed an agreement to acquire a third proprietary technology platform. The transaction, which closed in early January 2011, and the technology are discussed above under Recent Events.

## **Our Technology**

### ***CollaFix***

The CollaFix technology combines an innovative means of creating fibers from soluble collagen and a specialized cross-linking process. MiMedx utilizes two separate cross-linking technologies for various applications. Initial laboratory and animal testing shows that the cross-linked collagen fibers produce a very strong, biocompatible, and durable construct that can be transformed into surgical meshes intended to treat a number of orthopedic soft-tissue trauma and disease disorders.

Embodiments and benefits of products that we believe, based on preliminary studies, could be developed using this licensed technology are:

Initial tests of cross-linked fibers appear to demonstrate they are stronger than existing collagenous tissue, including healthy tendons and ligaments. These fibers form the fundamental unit from which a variety of devices could be configured as follows:

Linear and braided arrays for tendon and ligament repair

Cross-helical arrays forming tubular structures that also can be cut to form flat patches

Woven meshes for general surgical use;

CollaFix biomaterials have been tested and results preliminarily suggest that the materials are biocompatible and biodegradable;

Biocompatibilization (making a material biocompatible that may otherwise not be) of in-dwelling medical devices by coating with MiMedx proprietary NDGA (nordihydroguaiaretic acid) polymerized collagen;

NDGA treatment of xenograft (animal in origin) and allograft (human in origin) materials could make them more biocompatible and possibly improve functional lifetime; and

Cross-linked collagen-based biorivets have the potential to be used for bone fracture fixation.

Our core collagen technology is protected by patents, patent applications and trade secrets. The core patent covers the polymerization chemistry of NDGA as applied to biological materials, bioprotheses, or devices created through its application. It covers chemistries and compounds that have the reactive groups that are responsible for the effectiveness of NDGA, including a variety of organically synthesized NDGA analogs and natural compounds. Multiple medical products potentially could be developed and patented that are all tied to the core patented technology. Our core fiber technology is a closely held trade secret.

We are currently pursuing the manufacture and optimization of various collagen constructs and we are focused on advancing our products through the regulatory process to receive FDA clearance to introduce our products to the market.



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We may license rights to specific aspects of our collagen technology to third parties for use in applications and indications that we choose not to exploit ourselves.

### ***HydroFix***

We license rights to a PVA polymer, which is a water-based biomaterial that can be manufactured with a wide range of mechanical properties, including those that appear to mimic closely the mechanical and physical properties of natural, healthy human tissue. This hydrogel has been used in other orthopedic and general surgery device applications, and we believe it has demonstrated biocompatibility and durability inside the human body. Regulatory agencies both inside and outside the United States have cleared the hydrogel material for use inside the body for several applications. For example, in the United States, the FDA has cleared devices using the hydrogel material for use as a cover for vessels following anterior vertebral surgery as well as for use next to nerves. In the European Union and Canada, devices using the hydrogel material have been cleared for use next to nerves, to replace worn-out and lesioned cartilage in the knee, and as a post-surgical adhesion inhibiting barrier for spine surgeries in specific locations.

As mentioned above, on April 20, 2009, we received FDA clearance via a 510(k), for our Paradís Vaso Shield , recently renamed HydroFix Vaso Shield (the Vaso Shield ), which is a vessel guard made of our hydrogel material. Protection of veins and arteries is a common issue associated with many types of surgeries. Protection of the aorta, vena cava, iliac vessels and other anatomy is particularly important in anterior spine surgery. The HydroFix Vaso Shield was designed to help physicians protect vessels following anterior vertebral surgery. The FDA cleared the HydroFix Vaso Shield as a vessel guard or cover for anterior vertebral surgery, however, the safety and effectiveness of this device for reducing the incidence, severity and extent of post-operative adhesion formation has not been established.

We have a similar version of the product for the European market called HydroFix Spine Shield, which has received two CE marks. The device is classified as a post-surgical adhesion inhibiting barrier and is used in specific spine surgeries. The CE marking, also known as CE Mark, is a mandatory conformity mark on many products placed on the single market in the European Economic Area (EEA). The CE marking certifies that a product has met European Union (EU) consumer safety, health or environmental requirements. In December 2010, we received a second CE mark for HydroFix Spine Shield for use in contact with the central circulatory system and the central nervous system. The CE marked HydroFix Spine Shield is not available in the United States.

We are currently in the process of identifying other uses and indications for the HydroFix technologies, including, but not limited to, other areas of the spine as well as healthcare categories outside the spine, such as general surgery, obstetrics, and gynecology, maxilla-facial, plastic and cosmetic applications, and others.

### **Market Opportunity**

In 2008, the value of the Orthopedic-Biomaterials segment was estimated to be \$7.4 billion, representing over 20% of the total Orthopedic Market. It is estimated that this market segment will grow at over 13% per year, which is more than double the growth rate for the overall Orthopedics Market. The Biomaterials market is expected to grow to a value of \$9.4 billion in 2011, mainly due to advancements in materials science technology, the incidence of trauma and disease associated with the baby-boomer population and resource focus and investment (MedMarket Diligence, Report #M625, Emerging Trends, Technologies and Opportunities in the Markets for Orthopedic Biomaterials, Worldwide, 2008).

Orthopedics is one of the largest medical sectors utilizing biomaterials. The development of advanced generation products has prompted many orthopedic companies whose foundations lie in traditional therapies to focus on biomaterials due to physician and patient demand. We believe that new biomaterial products will continue to replace existing products.

The main orthopedic biomaterials markets driving growth are connective and soft tissues, such as tendon and ligament repair (tendons connect muscle to bone and ligaments connect bone to bone), meniscus repair, bone grafts, resorbable technologies, and cartilage repair.



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We believe that the number of procedures that might utilize our products is large. A 2009 iData report, US Market for Orthopedic Soft Tissue and Sports Medicine, stated that in 2009, the combined orthopedic soft tissue repair market was valued at over \$1.05B. In addition, another iData report, US Market for Spinal Implants, MIS and VCF, reported the total US spinal implant market in 2008 to be \$4.75B, a 9% growth over 2007.

Rotator cuff injuries represent a leading cause of shoulder instability and result in approximately 400,000 invasive procedures annually, according to MedTech Insight, an industry marketing research firm.

Also, the CollaFix biomaterials and related processes under license may prove suitable for use in general surgical procedures for reinforcement of soft tissue where weakness exists or scar tissue formation is not desirable.

The market revenue for biomaterials in wound care is expected to rise at an accelerated compound annual growth rate of 16.5% from 2006-2013. Combination products (biomaterial dressings that also possess moist dressing, antimicrobials, or alginates) are further driving growth and gaining market share from other advanced wound dressing segments, according to the Frost and Sullivan US Interactive Wound Care Markets Report for 2008.

***Tendon and Ligament Repair Technologies***

Advancements in tendon surgery have focused largely on augmenting the standard of care using synthetic and biomaterials including collagen based devices. Advancements in ligament surgery have focused largely on new methods of graft fixation using interference screws and anchors, which have opened new approaches to repair. We believe there is a new wave of development for ligament and tendon repair, including collagen matrices, allografts and tissue engineered tendons and ligaments that we believe will change how physicians treat these procedures.

Therapeutic modalities we continue to focus on are related to the treatment and repair of soft tissues during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons.

Following clinical development of the above, we plan to focus on treatments for ligaments and joints, such as medial and lateral collateral ligaments of the knee, elbow and ankle and meniscal repair. Our products potentially could be used in other orthopedic categories as well.

***PVA-Based Biomaterials***

Our PVA based biomaterial, HydroFix, has been used in several medical device applications and is cleared by the FDA for use as a cover for vessels following anterior vertebral surgery and for use as a nerve cuff (SaluMedica, LLC). We have licensed the right to use Salubria®, SaluMedica LLC's formulation, or similar PVA-based biomaterials for certain applications within the body under a world-wide license (see Collaborations and License Agreements). The material, as Salubria®, has been sold in Europe for certain applications for over seven years. The PVA-based hydrogel can be processed to have mechanical and physical properties similar to that of human tissue. The biostable hydrogel composition contains water in similar proportions to human tissue, mimicking human tissue's strength and compliance. For certain applications, the PVA-based hydrogel has been formulated to be wear-resistant and strong. The base organic polymer is known to be biocompatible and hydrophilic. These properties make it a candidate for use as an implant, and may prove suitable for development into medical products addressing various applications. The PVA-based hydrogel and products formed therefrom are MRI compatible (allowing for Magnetic Resonance Imaging of a patient with no artifacts or special safety precautions necessary). We currently license the PVA-based hydrogel for use in the spine, rotator cuff and as a surgical sheet.

***Spine Anatomy and Disorders***

The spine is considered by many orthopedic and neurosurgeons to be the most complex motion segment of the human body. It provides a balance between structural support and flexibility. It consists of 26 separate bones called vertebrae that are connected together by connective tissue to permit a normal range of motion. The spinal cord, the body's central nerve conduit, is enclosed within the spinal column. Vertebrae are paired into what are called motion segments that move by means of three joints: two facet joints and one spinal disc.

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The four major categories of spine disorders are degenerative conditions, deformities, trauma and tumors. The largest market is degenerative conditions of the vertebral discs. These conditions can result in instability, pressure and impingement on the nerve roots as they exit the spinal column, causing often severe and debilitating pain in the back, arms and/or legs.

***Current Treatments for Spine Disorders***

The current prescribed treatment for spine disorders depends on the severity and duration of the disorder. Initially, physicians typically prescribe non-operative procedures including bed rest, medication, lifestyle modification, exercise, physical therapy, chiropractic care and steroid injections. Non-operative treatment options are often effective; however, other patients require spine surgery. According to Knowledge Enterprises, Inc., the number of spine surgery procedures grew to over 1.2 million per year in 2005 in the United States. The most common spine surgery procedures are: discectomy, the removal of all or part of a damaged disc; laminectomy, the removal of all or part of a lamina, or thin layer of bone, to relieve pinching of the nerve and narrowing of the spinal canal; and fusion, where two or more adjoining vertebrae are fused together to provide stability.

***Spine Repair and Vessel Protection***

MedTech Insight, LLC's March 2007 report on United States Markets for Spinal Motion Preservation Devices, states that an estimated 50 million people in the United States suffer from back pain. This report also states that in 2004, more than 1 million spine surgeries were performed in the United States far more than the number of hip and knee replacements combined. Factors driving growth of the spine surgery products market include the growing number of people with degenerative disc disease, which typically is caused by gradual disc damage and often results in disc herniation and chronic, debilitating lower back pain. It is most common among otherwise healthy people in their 30s and 40s and affects approximately half of the United States population age 40 and older.

A disc herniation, or abnormal bulge or rupture, is often caused by degenerative disc disease but may also result from trauma and/or injury. As we age, the disc's *nucleus pulposus*, or the center of a spinal disc, loses its water content and the disc begins to degenerate, becoming drier, less flexible, and prone to damage or tears. By the time a person reaches age 80, the nucleus pulposus water content decreases to approximately 74%; during the first year of a person's life, the water content is approximately 90%. The *annulus fibrosus*, or the outer rim of a spinal disc, also may be damaged by general wear and tear or by injury and can cause bulging and impingement on adjacent nerve roots.

Repair of herniated intervertebral discs or damage as a result of degenerative disc disease commonly involves surgical intervention such as fusion or total disc replacement (TDR). Postsurgical adhesions and fibrosis formation are a common consequence of the normal healing process. The presence of fibrosis may render reoperations or follow-up surgeries risky and have caused nerve root tethering in some patients.

One approach to protecting vessels following anterior vertebral surgery is to provide a barrier between the anterior spine and adjacent vessels. Some studies, not performed by us, have demonstrated that the application of a barrier to protect adjacent vessels may create a dissection plane for future surgeries in that anatomical area.

The safety and effectiveness of the FDA cleared HydroFix Vaso Shield device for reducing the incidence, severity and extent of post-operative adhesion formation has not been established.

Another market for which a barrier or plane of dissection-type product is needed is in gynecological uses where the removal and surgical cutting of fibroids and cysts, hysterectomies, and other procedures may lead to post-surgical adhesions. Such adhesions may result in infertility and pelvic pain. Gynecological surgery provides a compelling market because of the high volume of procedures worldwide, and because gynecological infertility surgery is frequently followed up by a laparoscopic second-look procedure at the disease site.

There are many other medical categories for which scar-tissue and fibrosis formation are complicating issues and the Company is researching opportunities for expansion of this product platform.

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### **Medical Advisory Board**

We have empanelled a number of key scientists and physician opinion leaders in relevant fields by asking them to serve on our Medical Advisory Board ( MAB ). Each has entered into a consulting agreement with the Company. Our MAB includes scientists and physicians who move medicine forward by scientific endeavor, such as publishing, teaching and developing new solutions to treat injury and diseases. Several members chair their respective departments at university medical schools, teaching institutions and fellowship programs.

One of the most well-known of our MAB members is James Andrews, M.D., of Birmingham, Alabama, and Gulf Breeze, Florida. Dr. Andrews is one of the most respected sports-medicine physicians in the world. He is the physician for several National Football League and Major League Baseball teams and treats many of the highest-paid professional athletes from numerous teams and from a multitude of sports, including Drew Brees, the 2010 Superbowl MVP, and is regularly profiled in newspapers and magazines. Dr. Andrews also runs a sought-after fellowship program.

The MAB consists of 14 individuals and is grouped by specialty. Robert Guldberg, Ph.D. is working with us in all of our concentration areas, spine, sports medicine and upper and lower extremities. Others that are advising us in the spine area are: Richard Guyer, MD; Paul Jeffords, MD; Thomas Terrimani, MD; and Thomas Zdeblick, MD. Our Sports Medicine group consists of James Andrews, MD; Neal ElAttrache, MD; Timothy Kremcheck, MD; and Lonnie Paulos, MD. The Upper and Lower extremity group includes Martin Boyer, MD; Glenn Gaston, MD; Mark Glazebrook, MD; Jeff Johnson, MD and Gary Lourie, MD.

### **Government Regulation**

Our products are medical devices subject to extensive regulation by the FDA, under the Federal Food, Drug, and Cosmetic Act and they are also regulated in the European Union through the Medical Device Directive. Similar regulations apply in other countries. These regulations govern, among other things, the following activities:

- product design and development;
- product testing;
- product manufacturing;
- product labeling;
- product storage;
- premarket clearance or approval;
- advertising and promotion;
- product sales and distribution; and
- medical device reporting.

Each medical device that we distribute commercially in the U.S. likely will require either 510(k) clearance or Premarket Approval ( PMA ) from the FDA prior to marketing. Devices deemed to pose relatively less risk are placed in either Class I or II which requires the manufacturer to submit a premarket notification requesting permission for commercial distribution; this is known as 510(k) clearance, which indicates that the device is substantially equivalent to devices already legally on the market. Most Class I devices are considered very low risk and are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device or a pre-amendment Class III device for which PMA applications have not been required, are placed in Class III, requiring PMA approval.

Some of our products contain biologic materials. We believe that the FDA will regulate our products as medical devices. However, the FDA may determine that some of our products are combination products comprised of a biologic and medical device component. For a combination product, the FDA must determine which center or centers within the FDA will review the products and under what legal authority the products will be reviewed. While we believe our products would likely be regulated under the medical device authorities even if they are deemed combination products, there can be no assurances that the FDA will agree. In addition, the review of combination products is often more complex and more time consuming than the review of a product under the jurisdiction of only one center within the FDA.





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***510(k) Clearance Pathway***

To obtain 510(k) clearance for one of our products, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of PMA applications. The FDA's 510(k) clearance pathway usually takes from four to 12 months, but it can take significantly longer for submissions that include clinical data.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. As part of the PMA review, the FDA typically will inspect the manufacturer's facilities for compliance with Quality System Regulation, or QSR, requirements, which prescribe elaborate testing, control, documentation and other quality assurance procedures. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

***PMA Approval Pathway***

If 510(k) clearance is unavailable for one of our products, the product must follow the PMA approval pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction. The PMA approval pathway is much more costly, lengthy and uncertain. It generally takes from one to three years and can take even longer.

A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. As mentioned above, in conjunction with a PMA review, the FDA typically will inspect the manufacturer's facilities for compliance with QSR requirements, which prescribe elaborate testing, control, documentation and other quality assurance procedures.

Upon submission, the FDA determines if the PMA application is sufficiently complete to permit a substantive review, and, if so, the application is accepted for filing. The FDA then commences an in-depth review of the PMA application, which typically takes one to three years, but may take longer. The review time is often significantly extended as a result of the FDA asking for more information or clarification of information already provided. The FDA also may respond with a not approvable determination based on deficiencies in the application and require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years. During the review period, an FDA advisory committee may be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel's recommendation is important to the FDA's overall decision making process.

If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions (*e.g.*, changes in labeling) or specific additional information (*e.g.*, submission of final labeling) in order to secure final approval of the PMA application. Once the approvable letter is satisfied, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process.

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***Clinical Trials***

A clinical trial is generally required to support a PMA application and is sometimes required for a premarket notification. Such trials generally require submission of an application for an Investigational Device Exemption, or IDE. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients (unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements). Clinical trials are subject to extensive monitoring, record keeping and reporting requirements. Clinical trials may begin once the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites, and must comply with FDA regulations. To conduct a clinical trial, we also are required to obtain the patients' informed consent that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S.

***Post market***

After a device is placed on the market, numerous regulatory requirements apply. These include: the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or off-label uses; and the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. Class II devices also can have special controls such as performance standards, post market surveillance, patient registries, and FDA guidelines that do not apply to Class I devices.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions, and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or PMA approval of new products;
- withdrawing 510(k) clearance or PMA approvals already granted; and
- criminal prosecution.

The FDA also has the authority to require repair, replacement or refund of the cost of any medical device that we have manufactured or distributed.

***International***

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. In addition, the export of certain of our products that have not yet been cleared or approved for domestic distribution may be subject to FDA export restrictions. There can be no assurance that we will receive on a timely basis, if at all, any foreign government or United States export approvals necessary for the marketing of our products abroad.

The primary regulatory environment in Europe is that of the European Union, which consists of twenty-seven countries, encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear a CE Mark and can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by

the manufacturer and a third party assessment by a Notified Body. This third party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body in one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union.

**Table of Contents*****Export of Uncleared or Unapproved Devices***

Export of devices eligible for the 510(k) clearance process, but not yet cleared to market, is permitted without FDA approval, provided that certain requirements are met. Unapproved devices subject to the PMA process can be exported to any country without FDA approval provided that, among other things, they are not contrary to the laws of the country to which they are intended for import, they are manufactured in substantial compliance with the Quality System Regulations, and they have been granted valid marketing authorization by any member country of the European Union, Australia, Canada, Israel, Japan, New Zealand, Switzerland or South Africa. If these conditions are not met, FDA approval must be obtained, among other things, by demonstrating to the FDA that the product is approved for import into the country to which it is to be exported and, in some cases, by providing safety data for the device. There can be no assurance that the FDA will grant export approval when necessary or that countries to which the device is to be exported will approve the device for import. Our failure to obtain necessary FDA export authorization and/or import approval could have a material adverse effect on our business, financial condition and results of operation.

***Regulatory Status of our Products***

On April 20, 2009, the Company received FDA clearance to market the HydroFix Vaso Shield (formerly called Paradís Vaso Shield) device, indicated for use as a cover for vessels following anterior vertebral surgery. The proprietary, patented, and PVA based membrane may reduce the risk of associated injury following anterior vertebral surgeries by providing a vessel cover. We have products under development that may qualify for 510(k) clearance, such as our collagen fiber implants and additional sheet products made from PVA-based hydrogel. In 2010, two HydroFix 510(k) submissions were cleared in the U.S. Additionally, two HydroFix CE Marks (European clearance) were issued. One additional HydroFix 510(k) submission, one CollaFix collagen fiber 510(k) submission, and one CollaFix collagen fiber CE Mark submission were in process at the end of the year. No assurances can be made regarding the outcome of these in-process submissions or the timeframe needed for completion of the process.

**Reimbursement Procedures, Profitability and Costs**

Our products likely will be purchased by hospitals or ambulatory surgery centers that are reimbursed by third-party payers. In the U.S., such payers include governmental programs (e.g., Medicare and Medicaid), private insurance plans, managed care programs and workers compensation plans. Governmental payment programs have prescribed reimbursement rates for procedures and medical products. Similarly, private third-party payers have carefully negotiated payment levels for procedures and medical products. In addition, in the United States, an increasing percentage of insured individuals are receiving their medical care through managed care programs, which monitor and may require pre-approval of the services that a member will receive. Our success depends on adequate levels of third-party reimbursement for our products.

In those countries outside the U.S. where our products are approved for sale, we expect that sales volumes and prices of our products will be influenced by the availability of reimbursement from governments or third-party payers. If adequate levels of reimbursement from governments or third-party payers outside of the U.S. are not obtained, international sales of our products will be limited. Outside of the U.S., reimbursement systems vary significantly by country. Many foreign markets have government-managed health care systems that govern reimbursement for medical devices and procedures and often require special consideration for reimbursement for a new device.

We are currently working with industry reimbursement consultants to aid in the reimbursement planning for our products. At this time there can be no assurance that reimbursement policies will provide an acceptable return on our products.

**Competition*****CollaFix Products***

In the US in 2007, approximately 2,090,000 orthopedic soft tissue repair procedures were performed. This procedure volume is growing at a rate of 4.5% supported by the rising number of sports-related injuries, particularly among the increasingly active aging population. Source: US Markets for Orthopedic Soft Tissue Solutions 2008, Millennium Research Group

There are currently a large number of devices on the market used to reinforce surgically repaired soft tissues. These include hardware (screws, pins, disposables) as well as allografts, synthetic products and xenografts (derived from

porcine, bovine and equine tissues).

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*Leading Competitors in the Orthopedic Soft Tissue Solutions Market, as a % of Total, US, 2007.*

	Percent of US total Soft Tissue Market
Leading Competitors	
Arthrex	33.8%
DePuy Mitek	17.1%
Smith and Nephew	13.2%
CONMED Linvatec	5.8%
Genzyme Biosurgery	3.4%
Musculoskeletal Transplant Foundation	3.2%
Biomet Sports Medicine	3.1%
AlloSource	2.7%
ArthroCare	2.1%
LifeNet Health	1.9%
Other	13.7%

Source: US Markets for Orthopedic Soft Tissue Solutions 2008, Millennium Research Group

There are several technologies currently on the market or anticipated to enter the market for ligament and tendon repair and/or replacements. Those technologies include collagen matrices, cell-seeded polymer scaffolds, cryopreserved allografts, fibroblast-seeded ligament analogs, and small intestinal submucosa.

Competitors who market collagen based devices currently include:

<b>Developer</b>	<b>Product</b>	<b>Cross-linking</b>
DePuy	RESTORE	None
Wright Medical Technology	GraftJacket	None
Synovis	OrthAdapt	Carbodiimide
ReGen Biologics	Collagen matrices	None
Biomet/Organogenesis	CuffPatch	Carbodiimide

The above technologies may or may not utilize cross-linking agents, which are FDA-approved and used in the manufacturing of collagen for soft-tissue repair. The current market leader is the Restore Orthobiologic Soft Tissue Implant from DePuy. It utilizes small intestinal submucosa of porcine origin. We believe our collagen fiber-based devices will provide better reinforcement for tendon and ligament repair because they are made of high strength cross-linked collagen fibers and, by mimicking the natural fiber orientation in tendons and ligaments, they provide targeted mechanical properties equivalent to those of tendons and ligaments.

There are a few synthetic products, such as W.L. Gore's GoreTex, 3M Kennedy Ligament Augmentation Device (LAD), and Stryker's Meadox Dacron Ligament Augmentation Graft which were developed for use in Anterior Cruciate Ligament (ACL) reconstruction. These were first and second generation soft-tissue repair products and generally produce results that we believe are less satisfactory than those containing soft-tissue constructs, because the materials tend to stretch and become deformed over time.

**HydroFix Products**

Spinal orthopaedic and neurosurgeons actively seek treatment alternatives and utilize various technologies during different stages of the patient care continuum. Until the recent success of non-fusion technologies, spine implant market manufacturers have focused almost exclusively on refining and improving spinal fusion techniques. Multiple fusion techniques and products are available to patients today.



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Regardless of the type of surgery, fusion or TDR, physicians commonly deal with venous injury during anterior spinal revision surgery. Currently, competition for vessel guards for this specific application is limited. W.L. Gore & Associates, Inc. is the dominant manufacturer in this area.

**Collaborations and License Agreements**

***License Agreement between MiMedx, Shriners Hospitals for Children, and University of South Florida Research Foundation***

We entered into a license agreement with Shriners Hospitals for Children and University of South Florida Research Foundation (collectively Licensor) in January 2007 for the worldwide, exclusive rights for all applications using NDGA-polymerized materials, including for reconstruction of soft tissue. We paid a one-time license fee of \$100,000, plus issued to the Licensor 1,120,000 shares of our Common Stock, and the Licensor will receive future additional milestone payments and continuing royalties based on sales of all licensed products.

The license is perpetual and terminable by us at any time, in whole or in part. The licensor has the right to terminate this license in the event that any breach, which they are required to give us notice of, is not cured.

***License Agreement between SpineMedica and SaluMedica, LLC***

In August 2005 we entered into an exclusive, perpetual, worldwide, non-terminable, royalty-free, transferable license of certain patents and patent application rights held by SaluMedica, LLC that relate to a PVA-based hydrogel. SpineMedica has the right to manufacture, market, use and sell medical devices and products incorporating the claimed technology for all neurological and orthopedic uses related to the human spine, including muscular and skeletal uses. Some of the licensed patents and patent application rights are owned by SaluMedica, LLC and at least one of these patent and patent application rights is licensed by SaluMedica, LLC from Georgia Tech Research Corporation. In connection with this license agreement, SpineMedica also acquired certain of SaluMedica, LLC's assets, including manufacturing and testing equipment and office equipment, and obtained a license to use the trademarks SaluMedica and Salubria<sup>®</sup> biomaterial.

***License Agreement between SaluMedica, LLC and Georgia Tech Research Corporation***

Some of the patents and patent application rights licensed to SpineMedica by SaluMedica, LLC are licensed to SaluMedica, LLC from Georgia Tech Research Corporation. SaluMedica, LLC and Georgia Tech Research Corporation have agreed that in the event the license agreement between them is terminated for any reason (other than the expiration of the patents), Georgia Tech Research Corporation will license the technology to SpineMedica for uses related to the human spine on substantially the same terms as granted to SaluMedica, LLC without further payment.

***Rotator Cuff License with SaluMedica, LLC***

MiMedx has a Technology License Agreement, as amended by a First Amendment to Technology License Agreement, as well as a related Trademark License Agreement, all dated August 3, 2007, (collectively, the Rotator Cuff License) that provided MiMedx with the exclusive, fully-paid, worldwide, royalty-free, irrevocable and non-terminable (except as provided in the Rotator Cuff License), and sublicensable rights to develop, use, manufacture, market, and sell Salubria<sup>®</sup> biomaterial or similar PVA-based hydrogels for all neurological and orthopedic uses (including muscular and skeletal uses) related to the rotator cuff and the hand (excluding the wrist), but excluding the product SaluBridge (which is made from Salubria<sup>®</sup> biomaterial and is currently cleared for use by the FDA) (the Licensed Rotator Cuff IP). SaluMedica, LLC's rights in the Licensed Rotator Cuff IP derive from and are subject to one or more licenses from Georgia Tech Research Corporation and, consequently, the Rotator Cuff License is subject to those same licenses. This license was amended in October 2009 to relinquish the license for uses related to the hand but we kept the rotator cuff license.



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***Surgical Sheet License with SaluMedica, LLC***

On March 31, 2008, we entered into an exclusive world-wide license with SaluMedica, LLC for a PVA-based hydrogel biomaterial for applications as a surgical sheet. The license covers both internal and external applications. In exchange for the exclusive, worldwide, perpetual license to develop, manufacture, and sell the surgical sheet technology for application anywhere in the body, we issued SaluMedica, LLC 400,000 shares of restricted Common Stock. In addition, SaluMedica, LLC is eligible to receive up to an aggregate additional 600,000 shares of restricted Common Stock if certain sales and revenue milestones are achieved not later than June 30, 2013. On December 31, 2009, we completed the sale of our first commercial product, the HydroFix Vaso Shield, and met the first milestone under this agreement. As a result we issued 100,000 shares of Common Stock to the licensor valued at \$71,000.

***Intellectual Property***

Our intellectual property includes licensed patents, owned and licensed patent applications and patents pending, proprietary manufacturing processes and trade secrets, brands, trademarks and trade names associated with our technology. Furthermore, we require employees, consultants and advisors to sign Proprietary Information and Inventions Agreements as well as Nondisclosure Agreements that assign to us and protect the intellectual property existing and generated from their work and that we may use and own exclusively.

The pending and provisional patent applications may not issue into patents, as is true with any provisional or patent application.

Worldwide, the MiMedx CollaFix and HydroFix technologies are protected with 8 patents and 41 patent applications, as well as proprietary manufacturing processes and trade secrets.

***Improvements to Technology***

Any improvements to Salubria® developed by SaluMedica, LLC during the life of the licensed patents are included as part of the license from SaluMedica, LLC. The Company will own all improvements to Salubria® that we develop. However, we will license these improvements to SaluMedica, LLC for no additional consideration, provided that the use of these improvements must be unrelated to all neurological and orthopedic uses, including muscular and skeletal uses, related to the human spine.

***Trademarks & Trade Names***

We also own trademark and trade name registration of the mark Paradís Vaso Shield™ and license the SaluMedica and Salubria® trademarks. We also have applied for registration of the trademarks of MiMedx and our product names.

***Manufacturing***

MiMedx Group performs research and early stage product and process development activities and operates a pilot production facility for its proprietary CollaFix cross-linked collagen products in its Tampa, Florida, facility. In the future, we may contract with third parties to perform certain manufacturing or assembly of the products that are developed and enter into strategic relationships for sales and marketing of products that we develop.

Our Marietta, Georgia, facility is also our corporate headquarters, which houses our general management, sales, marketing, product development, quality and regulatory functions as well as the consolidation of our manufacturing operations for HydroFix and CollaFix.

We are subject to the FDA's quality system regulations, state regulations, and regulations promulgated by the European Union. We are FDA registered, CE marked and ISO certified. Our facilities are subject to periodic unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state and foreign agencies.

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### **Suppliers**

We have identified reliable sources and suppliers of collagen, source materials of NDGA, which we believe will provide a product in compliance with FDA guidelines. We engage in the manufacture of our own hydrogel products and accessibility to critical raw materials for the PVA-based biomaterial products is not inhibited by supply or market constraints.

### **Marketing and Sales**

We plan to utilize our experienced management team to commercialize these medical technologies by advancing them through the proper regulatory approval processes, developing or arranging for reliable and cost-effective manufacturing, and to either sell or license the product lines to others or market and sell the products ourselves. For our first U.S. product, HydroFix Vaso Shield, we have assembled a network of independent sales representatives and stocking distributors to sell our products domestically. We have assembled and are continuing to assemble a network of stocking distributors for our first European product, HydroFix Spine Shield.

### **Employees**

As of December 31, 2010, we had 36 employees, of whom 32 are full-time and 4 are part-time employees. We consider our relationships with our employees to be satisfactory. None of our employees is covered by a collective bargaining agreement.

### **Litigation**

We are not involved in any litigation, nor are we aware of any threatened litigation.

### **Research and Development**

Our research and development efforts are focused on developing products for various surgical and orthopedic markets using NDGA biomaterials, and development of other sheet based spine products and other sheet products using a PVA-based hydrogel. Our research and development staff currently consists of 12 full time and 2 part time employees. To support development, we have contracts with outside labs who aid us in our research and development process. Our research and development group has extensive experience in developing products related to our field of interest, and works with our Physician Advisory Boards to design products that are intended to improve patient outcomes, simplify techniques, shorten procedures, reduce hospitalization and rehabilitation times and, as a result, reduce costs. See Management's Discussion and Analysis of Financial Condition and Results of Operations at Item 7 below for information regarding expenditures for research and development in each of the last two fiscal years.

### **Surgeon Training and Education**

We devote significant resources to working with our Medical Advisory Boards. We believe that the most effective way to introduce and build market demand for our products will be by partnering with leading surgeons from around the globe in the use of our products. We have access to state-of-the-art cadaver operating theaters and other training facilities at some of the nation's leading medical institutions. We intend to continue to focus on working with leading surgeons in the United States. See Business-Medical Advisory Boards.

### **Available Information**

Our website address is [www.mimedx.com](http://www.mimedx.com). We make available on this website under Investor Relations SEC Filings, free of charge, our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports as soon as reasonably practicable after we electronically file or furnish such materials to the U.S. Securities and Exchange Commission (SEC). In addition, we post filings of Forms 3, 4, and 5 filed by our directors, executive officers and ten percent or more shareholders. We also make available on this website under the heading Investor Relations Corporate Governance our Audit Committee, Compensation Committee and Corporate Governance and Nominating Committee Charters as well as our Code of Business Conduct and Ethics. The reference to our website does not constitute incorporation by reference of any information contained at that site.

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**Item 1A. Risk Factors**

**Risks Related to Our Business and Industry**

***We are a high-risk startup venture.***

With the commercialization of our first products, we have transitioned from being a development company to an operating company. Nonetheless, most of our products are still in the early stages of development and deployment, and we have limited operating history. We do not currently have any material assets, other than cash, certain laboratory equipment, and certain intellectual property rights. Our business and prospects must be evaluated in light of the expenses, delays, uncertainties and complications typically encountered by businesses in our stage of development, many of which may be beyond our control. These include, but are not limited to, lack of sufficient capital, unanticipated problems, delays or expenses relating to product development, governmental approvals, and licensing and marketing activities, competition, technological changes and uncertain market acceptance. In addition, if we are unable to manage growth effectively, our operating results could be materially and adversely affected. We must overcome these and other business risks to be successful. Our efforts may not be successful. We may never be profitable. Therefore, investors could lose their entire investment.

***Most of our planned products are in the early stage of product development.***

Many of the possible products we have rights to have had only limited research in the fields of use we currently intend to commercialize. Our product candidates will require testing and regulatory clearances or approvals. Accordingly, most of the products we are developing are not yet ready for sale and may never be ready for sale. The successful development of any products is subject to the risks of failure inherent in product development. These risks include the possibilities that any or all of these proposed products or procedures are found to be ineffective or toxic, or otherwise fail to receive necessary regulatory clearances or approvals; that the proposed products or procedures are uneconomical to market or do not achieve broad market acceptance; that third parties hold proprietary rights that preclude us from marketing them; or third parties market a superior or equivalent product. We are unable to predict whether our research and development activities will result in any additional commercially viable products or procedures. Furthermore, due to the extended testing and regulatory review process required before marketing clearances or approvals can be obtained, the time frames for commercialization of any products or procedures are long and uncertain.

***Continuing disruptions in the overall economy and the credit and financial markets may adversely impact our ability to raise necessary additional capital.***

The capital and credit markets continue to be very volatile as a result of adverse conditions that have caused the failure and near failure of a number of large financial services companies. If the capital and credit markets continue to experience volatility and the availability of funds remains limited, it is possible that our ability to access the capital and credit markets may be limited or nonexistent because of these or other factors, and we require additional capital in the near future in order to continue operations.

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***We will need additional financing to meet our future capital requirements.***

We will require significant additional funds, either through additional equity or debt financings or collaborative agreements or from other sources to engage in research and development activities with respect to our potential product candidates and to establish the personnel necessary to successfully manage us. We believe that our current cash and cash equivalents and committed line of credit will be sufficient to meet our projected operating requirements for the next twelve months. However, obtaining the required regulatory approvals and clearances and the planned expansion of our business will be expensive and time-consuming and we will in the future seek funds from public and private stock or debt offerings, borrowings under lines of credit or other sources. Our capital requirements will depend on many factors, including:

- the revenue generated by sales of our products;
- the costs associated with expanding our sales and marketing efforts, including efforts to hire independent agents and sales representatives;
- the expenses we incur in developing and commercializing our products, including the cost of obtaining and maintaining FDA or other regulatory clearances and approvals; and
- general and administrative expenses.

As a result of these factors, we must raise additional funds now and in the future and such funds may not be available on favorable terms, or at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing shareholders may experience dilution and the new equity or debt securities we issue may have rights, preferences and privileges senior to those of our existing shareholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, obtain the required regulatory clearances or approvals, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our development and commercialization goals, which could have a material and adverse effect on our business, results of operations and financial condition.

We have a limited operating history. Further, we have incurred losses since inception. The actual extent of our future losses and the timing of profitability are highly uncertain, and we may never achieve profitable operations. The principal causes of our losses are likely to be primarily attributable to personnel costs, working capital costs, research and development costs, brand development costs and marketing and promotion costs. We may never achieve profitability.

***We are in a highly competitive industry and face competition from large, well-established medical device manufacturers as well as new market entrants.***

Competition from other medical device companies and from research and academic institutions is intense, expected to increase, subject to rapid change, and significantly affected by new product introductions and other market activities of industry participants. In addition to competing with universities and other research institutions in the development of products, technologies and processes, we compete with other companies in acquiring rights to products or technologies from those institutions. There can be no assurance that we can develop products that are more effective or achieve greater market acceptance than competitive products, or that our competitors will not succeed in developing or acquiring products and technologies that are more effective than those being developed by us, that would render our products and technologies less competitive or obsolete.

Our competitors enjoy several competitive advantages over us, including some or all of the following:

- products which have been approved by regulatory authorities for use in the United States and/or Europe and which are supported by long-term clinical data;
- significantly greater name recognition;
- established relations with surgeons, hospitals, other healthcare providers and third party payors;
- large and established distribution networks in the United States and/or in international markets;
- greater experience in obtaining and maintaining regulatory approvals and/or clearances from the United States Food and Drug Administration and other regulatory agencies;

more expansive portfolios of intellectual property rights; and  
greater financial, managerial and other resources for products research and development, sales and marketing  
efforts and protecting and enforcing intellectual property rights.

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Our competitors' products will compete directly with our products. In addition, our competitors as well as new market entrants may develop or acquire new treatments, products or procedures that will compete directly or indirectly with our products. The presence of this competition in our market may lead to pricing pressure which would make it more difficult to sell our products at a price that will make us profitable or prevent us from selling our products at all. Our failure to compete effectively would have a material and adverse effect on our business, results of operations and financial condition.

***Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain and may be inadequate, which would have a material and adverse effect on us.***

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology, including our licensed technology. These legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our pending United States and foreign patent applications (and those we have or will have licenses to) may not issue as patents in a form that will be advantageous to us or may issue and be subsequently successfully challenged by others and invalidated. In addition, our pending patent applications include claims to material aspects of our products and procedures that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may be able to design around our patents or develop products that provide outcomes that are comparable or even superior to ours. Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with some of our officers, employees, consultants and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. In the event a competitor infringes upon our licensed or pending patent or other intellectual property rights, enforcing those rights may be costly, uncertain, difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents rights against a challenge. The failure to obtain patents and/or protect our intellectual property rights could have a material and adverse effect on our business, results of operations, and financial condition.

***We may become subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from developing our products, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages.***

Third parties could, in the future, assert infringement or misappropriation claims against us with respect to products we develop. Whether a product infringes a patent or misappropriates other intellectual property involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of others. Our potential competitors may assert that some aspect of our product infringes their patents. Because patent applications may take years to issue, there also may be applications now pending of which we are unaware that may later result in issued patents that our products infringe. There also may be existing patents or pending patent applications of which we are unaware that our products may inadvertently infringe.

Any infringement or misappropriation claim could cause us to incur significant costs, place significant strain on our financial resources, divert management's attention from our business and harm our reputation. If the relevant patents in such claim were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling any product that is found to infringe unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain such a license on terms acceptable to us, if at all, and we may not be able to redesign our products to avoid infringement. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin

us and our customers from making, using, or selling products, and could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

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***Our patents and licenses may be subject to challenge on validity grounds, and our patent applications may be rejected.***

We rely on our patents, patent applications, licenses and other intellectual property rights to give us a competitive advantage. Whether a patent is valid, or whether a patent application should be granted, is a complex matter of science and law, and therefore we cannot be certain that, if challenged, our patents, patent applications and/or other intellectual property rights would be upheld. If one or more of those patents, patent applications, licenses and other intellectual property rights are invalidated, rejected or found unenforceable, that could reduce or eliminate any competitive advantage we might otherwise have had.

***The prosecution and enforcement of patents licensed to us by third parties are not within our control, and without these technologies, our product may not be successful and our business would be harmed if the patents were infringed or misappropriated without action by such third parties.***

We have obtained licenses from third parties for patents and patent application rights related to the products we are developing, allowing us to use intellectual property rights owned by or licensed to these third parties. We do not control the maintenance, prosecution, enforcement or strategy for many of these patents or patent application rights and as such are dependent in part on the owners of the intellectual property rights to maintain their viability. Without access to these technologies or suitable design-around or alternative technology options, our ability to conduct our business could be impaired significantly.

***Our NDGA License Agreement could be terminated.***

Under our license agreement with Shriners Hospitals for Children and University of South Florida Research Foundation dated January 29, 2007, it is possible for the licensor to terminate the agreement if we breach the license agreement and all of our cure rights are exhausted. If our license agreement were to be terminated, it would have a negative impact on our business.

***We may be subject to damages resulting from claims that we, our employees, or our independent contractors have wrongfully used or disclosed alleged trade secrets of others.***

Some of our employees were previously employed at other medical device companies. We may also hire additional employees who are currently employed at other medical device companies, including our competitors. Additionally, consultants or other independent agents with which we may contract may be or have been in a contractual arrangement with one or more of our competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or independent contractors have used or disclosed any party's trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail to defend such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to market existing or new products, which could severely harm our business.

***SaluMedica, LLC may license the PVA-based hydrogel, the material used to make MiMedx's HydroFix products and other products we are developing, and its trademark to third parties for use in applications unrelated to the spine, rotator cuff, or surgical sheet applications. This may expose us to adverse publicity if these uses are not proven safe and effective.***

Our licenses with SaluMedica, LLC allows us to use technology and/or know-how related to the material used to manufacture applications related to the spine, rotator cuff and surgical sheet, and allows us to use the Salubria® biomaterial trademark. SaluMedica, LLC may license the PVA-based hydrogel and rights related to the Salubria® biomaterial trademark to third parties for applications not related to the spine, rotator cuff, or surgical sheet. If the use of Salubria® biomaterial or the PVA-based hydrogel by these third parties results in product liability claims or has other adverse effects in patients, surgeons and patients may associate these claims and effects with our products, even if our products are nevertheless proven safe and effective. If Salubria® biomaterial experiences adverse publicity or is not proven safe and effective in other applications, sales of our products could be adversely affected.





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***We depend on key personnel.***

Our success will depend, in part, upon our ability to attract and retain additional skilled personnel, which will require substantial additional funds. There can be no assurance that we will be able to find and attract additional qualified employees or retain any such personnel. Our inability to hire qualified personnel, the loss of services of our key personnel, or the loss of services of executive officers or key employees that that may be hired in the future may have a material and adverse effect on our business.

***Our operating results may fluctuate significantly as a result of a variety of factors, many of which are outside of our control.***

We are subject to the following factors, among others, that may negatively affect our operating results:

- the announcement or introduction of new products by our competitors;
- our ability to upgrade and develop our systems and infrastructure to accommodate growth;
- our ability to attract and retain key personnel in a timely and cost effective manner;
- technical difficulties;
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business, operations and infrastructure;
- regulation by federal, state or local governments; and
- general economic conditions as well as economic conditions specific to the healthcare industry.

As a result of our limited operating history, limited resources, and the nature of the markets in which we compete, it is extremely difficult for us to forecast accurately. We have based our current and future expense levels largely on our investment plans and estimates of future events although certain of our expense levels are, to a large extent, fixed. We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall.

Accordingly, any significant shortfall in revenue relative to our planned expenditures would have an immediate adverse effect on our business, results of operations and financial condition. Further, as a strategic response to changes in the competitive environment, the Company may from time to time make certain pricing, service or marketing decisions that could have a material and adverse effect on our business, results of operations and financial condition. Due to the foregoing factors, our revenue and operating results are and will remain difficult to forecast.

***The failure of government health administrators and private health insurers to reimburse patients for costs of services incorporating our current or potential products would materially and adversely affect our business.***

Our success depends, in part, on the extent to which reimbursement for the costs of products to users will be available from government health administration authorities, private health insurers and other organizations. Significant uncertainty usually exists as to the reimbursement status of newly approved healthcare products. Adequate third party insurance coverage may be unavailable for us, our sublicensees or partners to establish and maintain price levels sufficient for realization of an appropriate return on investment. Government and other third-party payers attempt to contain healthcare costs by limiting both coverage and the level of reimbursement of new products. Therefore, we cannot be certain that our products or the procedures performed with them will be covered or adequately reimbursed and thus we may be unable to sell our products profitably if third-party payors deny coverage or reduce their levels of payment below that which we project, or if our production costs increase at a greater rate than payment levels. If government and other third party payers do not provide adequate coverage and reimbursement for uses of the products incorporating our technology, the market's acceptance of our products could be adversely affected.

***Disruption of our manufacturing could adversely affect our business, financial condition and results of operations.***

Our results of operations are dependent upon the continued operation of our manufacturing facilities. The operation of biomedical manufacturing plants involves many risks. Such risks include the risks of breakdown, failure or substandard performance of equipment, the occurrence of natural and other disasters, and the need to comply with the requirements of directives from government agencies, including the FDA. The occurrence of material operational problems could have a material adverse effect on our business, financial condition, and results of operations during the period of such operational difficulties.



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***We currently have only one product cleared by the FDA for marketing, and may never develop or launch, any commercialized products.***

We have had only limited sales. We have invested substantial time and resources in developing various additional products. Commercialization of these products, including collagen fiber and PVA-based hydrogel products, will require additional development, clinical evaluation, regulatory clearance or approval, significant marketing efforts and substantial additional investment before they can provide us with any revenue. Despite our efforts, our products may not become commercially successful products for a number of reasons, including:

- we may not be able to obtain regulatory clearance or approvals for our products, or the approved indication may be narrower than we seek;
- our products may not prove to be safe and effective in preclinical or clinical trials;
- physicians or hospitals may not receive any reimbursement from third party payors, or the level of reimbursement may be insufficient to support widespread adoption of our products;
- we may experience delays in our development program;
- any products that are approved may not be accepted in the marketplace by physicians or patients;
- we may not be able to manufacture any of our products in commercial quantities or at an acceptable cost;
- and
- rapid technological change may make our products obsolete.

***We face the risk of product liability claims or recalls and may not be able to obtain or maintain adequate product liability insurance.***

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices, including those that may arise from the misuse or malfunction of, or design flaws in, our products. We may be subject to such claims if our products cause, or appear to have caused, an injury. Claims may be made by patients, healthcare providers or others selling our products. Defending a lawsuit, regardless of merit, could be costly, divert management attention and result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market.

Although we have product liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. If we are unable to maintain product liability insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims, we could be exposed to significant liabilities, which may harm our business. A product liability claim or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

***If we are unable to sell, market and distribute our products, our business may be harmed.***

To achieve commercial success for our products, we must develop a sales and marketing force, or enter into arrangements with others to market and sell our products. In addition to being expensive, developing such a sales force is time consuming, and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. Qualified direct sales personnel with experience in the medical device market are in high demand, and there is no assurance that we will be able to hire or retain an effective direct sales team. Similarly, qualified independent medical device representatives both within and outside the United States are in high demand, and we may not be able to build an effective network for the distribution of our product through such representatives. We have no assurance that we will be able to enter into contracts with representatives on terms acceptable to us, or if we do, we may be subject to a number of risks, including:

- We may be required to relinquish important rights to our products;
- We may not be able to control the amount and timing of resources that our distributors may devote to the commercialization of our products;
- Our distributors may experience financial difficulties; and
- Business combinations or significant changes in a distributor's business strategy may also adversely affect a distributor's willingness or ability to complete its obligations under any arrangement.

Failure to market and distribute products to our customers in a timely and cost effective manner would cause our potential sales to decrease and our margins to fall.



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***Off-label promotion of our products could result in substantial penalties.***

We are only permitted to promote our products in the U.S. for the uses indicated on the respective label as cleared by the FDA. The U.S. Attorneys' offices and other regulators, in addition to the FDA, have recently focused substantial attention on off-label promotional activities and have initiated civil and criminal investigations related to such practices. If it is determined by these or other regulators that we have promoted our products for off-label use, we could be subject to fines, legal proceedings, injunctions or other penalties.

***To be commercially successful, we must convince surgeons that our products are safe and effective alternatives to existing surgical treatments and that our products should be used in their procedures.***

We believe surgeons may not widely adopt our products unless they determine, based on experience, clinical data and published peer reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to conventional methods. Surgeons may be slow to change their medical treatment practices for the following reasons, among others:

- their lack of experience with prior procedures in the field using our products;
- lack of evidence supporting additional patient benefits and our products over conventional methods;
- perceived liability risks generally associated with the use of new products and procedures;
- limited availability of reimbursement from third party payors; and
- the time that must be dedicated to training.

In addition, we believe recommendations for and support of our products by influential surgeons are essential for market acceptance and adoption. If we do not receive this support or if we are unable to demonstrate favorable long-term clinical data, surgeons and hospitals may not use our products which would significantly reduce our ability to achieve expected revenue and would prevent us from becoming profitable.

***Any failure in our efforts to train surgeons could significantly reduce the market acceptance of our products.***

There will be a learning process involved for surgeons to become proficient in the use of our products. It will be critical to the success of our commercialization efforts to train a sufficient number of surgeons and to provide them with adequate instruction in the use of our products. This training process may take longer than expected and may therefore affect our ability to generate sales. Convincing surgeons to dedicate the time and energy necessary for adequate training is challenging and we may not be successful in these efforts. If surgeons are not properly trained, they may misuse or ineffectively use our products. This may result in unsatisfactory patient outcomes, patient injury, negative publicity, or lawsuits against us, any of which could have an adverse effect on our business.

***We depend on a single or a limited number of third-party suppliers, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could adversely affect our business.***

We rely on a limited number of third-party suppliers for the raw materials required for the production of our implant products. Furthermore, in some cases we rely on a single supplier. Our dependence on a limited number of third-party suppliers or on a single supplier, and the challenges we may face in obtaining adequate supplies of raw materials, involve several risks, including limited control over pricing, availability, quality, and delivery schedules. We cannot be certain that our current suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, could be identified and qualified. Although we believe there are other suppliers of these raw materials, we may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and commercialization of our products, including limiting supplies necessary for clinical trials and regulatory approvals, or interrupt production of the existing products that are already marketed, which would have a material adverse effect on our business.

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We also use collagen, a protein obtained from animal source tissue, as another significant material required to produce our products. We may not be able to obtain adequate supplies of animal source tissue, or to obtain this tissue from animal herds that we believe do not involve pathogen contamination risks, to meet our future needs or on a cost-effective basis. Any significant supply interruption could adversely affect the production of our products and delay our product development or clinical trial programs. These delays would have an adverse effect on our business.

***We will need to increase the size of our organization, and we may be unable to manage rapid growth effectively.***

Our failure to manage growth effectively could have a material and adverse effect on our business, results of operations and financial condition. We anticipate that a period of significant expansion will be required to address possible other acquisitions of business, products, or rights, and potential internal growth to handle licensing and research activities. This expansion will place a significant strain on management, operational and financial resources. To manage the expected growth of our operations and personnel, we must both modify our existing operational and financial systems, procedures and controls and implement new systems, procedures and controls. We must also expand our finance, administrative, and operations staff. Our current personnel, systems, procedures and controls may not adequately support our future operations. Management may be unable to hire, train, retain, motivate and manage necessary personnel or to identify, manage and exploit existing and potential strategic relationships and market opportunities.

***Our business could be materially and adversely impacted by risks inherent in international markets.***

We expect a significant percentage of our revenue to be from sales to customers outside the U.S. International sales subject us to inherent risks related to changes in the economic, political, legal and business environments in the foreign countries in which we do business, including the following:

Fluctuations in currency exchange rates;

Regulatory, product approval and reimbursement requirements;

Tariffs and other trade barriers;

Greater difficulty in accounts receivable collection and longer collection periods;

Difficulties and costs of managing foreign distributors;

Reduced protection for intellectual property rights in some countries;

Burdens of complying with a wide variety of foreign laws;

The impact of recessions in economics outside the U.S.; and

Political and economic instability

U.S. Export regulatory restrictions

If we fail to successfully market and sell our products in international markets, our business, financial condition, results of operations and cash flows could be materially and adversely affected.

***Recent and future acquisitions may cause integration problems, disrupt our business and strain our resources.***

In early 2011, we made a strategic business acquisition, and may continue with such acquisitions in the future. Our success will depend, to a certain extent, on the future performance of these acquired business entities. These acquisitions, either individually or as a whole, could divert management attention from other business concerns and expose us to unforeseen liabilities or risks associated with entering new markets and integrating these new entities. Further, the integration of these entities may cause us to lose key employees or key customers. Integrating newly acquired organizations and technologies could be expensive and time consuming and may strain our resources.

Consequently, we may not be successful in integrating these acquired businesses or technologies and may not achieve anticipated revenue and cost benefits.



**Table of Contents****Risks Related to Regulatory Approval of Our Products and Other Government Regulations**

***Government regulation of our business is extensive and obtaining and maintaining the necessary regulatory approvals is uncertain, expensive and time-consuming.***

The process of obtaining regulatory clearances or approvals to market a medical device from the FDA, or similar regulatory authorities outside of the United States is costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, or at all. The FDA's 510(k) clearance process generally takes 30 days to 6 months from submission, depending on whether a Special or traditional 510(k) premarket notification has been submitted, but can take significantly longer. An application for premarket approval, or PMA, must be submitted to the FDA if the device cannot be cleared through the 510(k) clearance process and is not exempt from premarket review by the FDA. The PMA process almost always requires one or more clinical trials and can take one to three years from the date of filing, or longer. In some cases, the FDA has indicated that it will require clinical data as part of the 510(k) process.

There is no certainty that any of our products will be cleared by the FDA by means of either a 510(k) notice or a PMA application. Even if the FDA permits us to use the 510(k) clearance process, we cannot assure you that the FDA will not require either supporting data from laboratory tests or studies that we have not conducted, or substantial supporting clinical data. If we are unable to use the 510(k) clearance process for any of our products, are required to provide clinical data or laboratory data that we do not possess to support our 510(k) premarket notifications for any of these products, or otherwise experience delays in obtaining or fail to obtain regulatory clearances, the commercialization of such product will be delayed or prevented, which will adversely affect our ability to generate revenue. It also may result in the loss of potential competitive advantages that we might otherwise attain by bringing our products to market earlier than our competitors. Any of these contingencies could adversely affect our business. Even if regulatory clearance is obtained, a marketed product is subject to continual review, and later discovery of previously unidentified problems or failure to comply with the applicable regulatory requirements may result in restrictions on a product's marketing, recalls, or withdrawal of the product from the market as well as possible civil or criminal sanctions.

***We expect to be required to conduct clinical trials for some of our products. We have no experience conducting clinical trials, they may proceed more slowly than anticipated, and we cannot be certain that our products will be shown to be safe and effective for human use.***

In order to commercialize some of our products, we may be required to submit a PMA, which will require us to conduct clinical trials. Even if we seek FDA clearance of one of our products through the 510(k) process, the FDA may require us to conduct a clinical trial in support of our 510(k). We will receive approval from the FDA to commercialize products requiring a clinical trial only if we can demonstrate to the satisfaction of the FDA, in well-designed and properly conducted clinical trials, that our product candidates are safe and effective and otherwise meet the appropriate standards required for approval for specified indications. Clinical trials are complex, expensive, time consuming, uncertain and subject to substantial and unanticipated delays. Before we may begin clinical trials that present a significant risk to subjects, we must submit and obtain FDA approval of an investigational device exemption, or IDE, that describes, among other things, the manufacture of, and controls for, the device and a complete investigational plan. Clinical trials may involve a substantial number of patients in a multi-year study. We may encounter problems with our clinical trials and any of those problems could cause us or the FDA to suspend those trials, or delay the analysis of the data derived from them.

A number of events or factors, including any of the following, could delay or prevent the completion of our clinical trials in the future and negatively impact or even foreclose our ability to obtain FDA approval for, and to introduce a particular product:

- failure to obtain approval from the FDA or any foreign regulatory authority to commence an investigational study;
- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining or in our maintaining required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;

insufficient supply of our products or other materials necessary to conduct our clinical trials;  
difficulties in enrolling patients in our clinical trials;  
negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical studies;  
serious or unexpected side effects experienced by patients in whom our products are implanted; or  
failure by any of our third-party contractors or investigators to comply with regulatory requirements or meet other contractual obligations in a timely manner.

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Our clinical trials may not begin as planned, may need to be redesigned, and may not be completed on schedule, if at all. Delays in our clinical trials may result in increased development costs for our product candidates, which could cause our stock price to decline and limit our ability to obtain additional financing. In addition, if one or more of our clinical trials are delayed, competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

There may be unexpected findings, particularly those that may only become evident from larger scale clinical trials, as compared with the smaller scale tests we intend to do initially. The occurrence of unexpected findings in connection with our clinical trials or any subsequent clinical trial required by our regulators may prevent or delay obtaining regulatory approval, and may adversely affect coverage or reimbursement determinations. Our regulators may also determine that additional clinical trials are necessary, in which case approval may be delayed for several months or even years while these trials are conducted. The clinical trials may not show that products we develop are safe and effective. If we are unable to complete the clinical trials necessary to successfully support our regulatory applications, our ability to commercialize our products, business, financial condition, and results of operations would be materially adversely affected.

### ***Our products contain biologic materials, and so may face additional obstacles to FDA clearance or approval.***

To complete successful clinical trials, a product must meet the criteria for clinical approval, or endpoints, established in the clinical study. These endpoints are established in consultation with the FDA, following any applicable clinical trial design guidelines, to establish the safety and effectiveness for approval of devices subject to PMA approval, or to demonstrate the substantial equivalence of devices subject to 510(k) clearance. However, in the case of products which are novel or which target parts of the human body for which there are no FDA approved products, the scientific literature may not be as complete and there may not be established guidelines for the design of studies to demonstrate the effectiveness of such products. As a result, clinical trials considering such products may take longer than average and obtaining approval may be more difficult. Additionally, the endpoints established for such a clinical trial might be inadequate to demonstrate the safety and efficacy or substantial equivalence required for regulatory clearance because they do not adequately measure the clinical benefit of the product being tested. In certain cases additional data collected in the clinical trial or further clinical trials may be required by the FDA. Any delays in regulatory approval will delay commercialization of our products, which may have an adverse effect on our business.

The FDA regulates human therapeutic products in one of three broad categories: drugs, biologics or medical devices. The FDA's scrutiny of products containing biologic materials may be heightened. Although we anticipate that most of our products under development will be regulated in the U.S. as medical devices, we will use biological materials in the production of several devices. FDA may conclude that some of our products are combinations of devices and biologics, or may conclude that some of our products are biologics rather than devices, potentially requiring a different and more time consuming premarket clearance mechanism. Use of this biological material in our products may result in heightened scrutiny of such product which may result in further delays in, or obstacles to, obtaining FDA clearance or approval.

### ***Subsequent modifications to our products may require new regulatory approvals, or may require us to cease marketing or recall the modified products until approvals are obtained.***

Once our products receive FDA approval or clearance, subsequent modification to our products may require new regulatory approvals or clearances, including 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification does not require a new clearance or approval. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We may make modifications that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.



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If a manufacturer determines that a modification to a FDA-cleared device requires premarket clearance, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application supplement. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

***If we or our suppliers fail to comply with the FDA's quality system regulations, the manufacture of our products could be delayed.***

We and our suppliers are required to comply with the FDA's quality system regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the quality system regulation through inspections. If we or our supplier fail a quality system regulations inspection or if any corrective action plan is not sufficient, FDA could take enforcement action, including any of the following sanctions and the manufacture of our products could be delayed or terminated:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

***We and our sales personnel, whether employed by us or by others, must comply with various federal and state anti-kickback, self-referral, false claims and similar laws, any breach of which could cause a material adverse effect on our business, financial condition and results of operations.***

Our relationships with surgeons, hospitals and the marketers of our products are subject to scrutiny under various federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to claims that the relevant law has been violated. Possible sanctions for violation of these fraud and abuse laws include monetary fines, civil and criminal penalties, exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers' compensation programs and TRICARE (the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents, retirees and their dependents), and forfeiture of amounts collected in violation of such prohibitions. Certain states have similar fraud and abuse laws, imposing substantial penalties for violations. Any government investigation or a finding of a violation of these laws would likely result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations.

Anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare programs. We have formed a Medical Advisory Board consisting of an aggregate of over 14 physicians and scientists to assist us with scientific research and development and to help us evaluate technologies. We have also entered into consulting agreements and product development agreements with surgeons, including some who may make referrals to us or order our products after our products are introduced to market. In addition, some of these physicians own our stock, which they purchased in arms-length transactions on terms identical to those offered to non-surgeons, or received stock options from us as consideration for consulting services performed by them. We also may engage additional physicians on a consulting basis. While these transactions were structured with the intention of complying with all applicable laws, including the federal ban on physician self-referrals, commonly known as the Stark Law,

state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties, or prohibit us from accepting referrals from these surgeons. Because our strategy relies on the involvement of physicians who consult with us on the design of our product candidates, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with our physician advisors who refer or order our products to be in violation of applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of our physician advisors. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from federally funded healthcare programs, including Medicare and Medicaid, for non-compliance.

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The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. There can be no assurance that federal or state regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether these changes are retroactive or will have effect on a going-forward basis only.

***We face significant uncertainty in the industry due to government healthcare reform.***

Political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. Reforms being implemented or under consideration in the United States include mandated basic healthcare benefits, controls on healthcare spending, increases in insurance premiums and increased out-of-pocket requirements for patients, the creation of large group purchasing organizations that aim to reduce the costs of products that their member hospitals consume, and significant modifications to the healthcare delivery system. We anticipate that the U.S. Congress and state legislatures will continue to review and assess alternative healthcare delivery systems and payment methods. Due to uncertainties regarding the ultimate features of reform initiatives and the timing of their enactment and implementation, we cannot predict which, if any, of such reform proposals will be adopted, when they may be adopted or what impact reform initiatives may have on us.

**Risks Related to the Securities Markets and Ownership of Our Common Stock*****The price of our Common Stock has been, and will likely continue to be, volatile.***

The market price of our Common Stock, like that of the securities of many other companies that are in, or are just emerging from, the development stage, has fluctuated over a wide range and it is likely that the price of our Common Stock will fluctuate in the future. Over the past two fiscal years, the closing price of our Common Stock, as reported by the OTC Bulletin Board, has fluctuated from a low of \$.40 to a high of \$6.35. The market price of our Common Stock could be impacted by a variety of factors, including:

- Fluctuations in stock market prices and trading volumes of similar companies or of the markets generally;
- Our ability to successfully launch, market and earn significant revenue from our products;
- Our ability to obtain additional financing to support our continuing operations;
- Disclosure of the details and results of regulatory applications and proceedings;
- Changes in government regulation;
- Additions or departures of key personnel;
- Our investments in research and development or other corporate resources;
- Announcements of technological innovations or new commercial products or services by us or our competitors;
- Developments in the patents or other proprietary rights owned or licensed by us or our competitors;
- The timing of new product introductions;
- Actual or anticipated fluctuations in our operating results, including any restatements of previously reported results;
- Our ability to effectively and consistently manufacture our products and avoid costs associated with the recall of defective or potentially defective products;
- Our ability and the ability of our distribution partners to market and sell our products;
- Changes in distribution channels; and
- The ability of our vendors to effectively and timely deliver necessary materials and product components.

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Further, due to the relatively fixed nature of most of our costs, which primarily include personnel costs as well as facilities costs, any unanticipated shortfall in revenue in any fiscal quarter would have an adverse effect on our results of operations in that quarter. Accordingly, our operating results for any particular quarter may not be indicative of results for future periods and should not be relied upon as an indication of our future performance. These fluctuations could cause the trading price of our stock to be negatively affected. Our quarterly operating results have varied substantially in the past and may vary substantially in the future. In addition, the stock market has been very volatile, particularly on the OTC Bulletin Board where our stock is quoted. This volatility is often not related to the operating performance of companies listed thereon and will probably continue in the foreseeable future.

***The concentrated Common Stock ownership by certain of our executive officers and directors will limit your ability to influence corporate matters.***

As of December 31, 2010, our directors and executive officers together beneficially owned approximately 29% of our outstanding Common Stock. This group has significant influence over our management and affairs and overall matters requiring shareholder approval, including the election of directors and significant corporate transactions, such as a merger or sale of our company or our assets, for the foreseeable future. This concentrated control will limit the ability of other shareholders to influence corporate matters and, as a result, we may take actions that some of its shareholders do not view as beneficial. In addition, such concentrated control could discourage others from initiating changes of control. As a result, the market price of our shares could be adversely affected.

***The exercise of warrants or options or conversion of notes may depress our stock price and may result in dilution to our common stockholders.***

There are a significant number of outstanding warrants and options to purchase our stock and there are a certain number of outstanding notes that are convertible into our Common Stock. If the market price of our Common Stock rises above the exercise price of outstanding warrants and options or the conversion price of the outstanding notes, holders of those securities may be likely to exercise their warrants and options or convert their notes and sell the Common Stock acquired upon exercise or conversion of such securities, as applicable, in the open market. Sales of a substantial number of shares of our Common Stock in the public market by holders of warrants, options, or notes may depress the prevailing market price for our Common Stock and could impair our ability to raise capital through the future sale of our equity securities. Additionally, if the holders of outstanding options, warrants, or notes exercise those options or warrants or convert those notes, as applicable, our common stockholders will incur dilution in their relative percentage ownership.

As of December 31, 2010, warrants to purchase 6,003,924 shares of our common stock at a weighted average exercise price of \$1.21 per share were outstanding and exercisable; options to purchase 8,257,650 shares of common stock were outstanding, of which 6,041,220 were exercisable at a weighted average exercise price of \$1.31 per share; and notes convertible into 403,000 shares of common stock at a conversion price of \$1.00 per share were outstanding.

***Our Common Stock is and likely will remain subject to the SEC's Penny Stock rules, which may make its shares more difficult to sell.***

Because the price of our Common Stock is currently and may remain less than \$5.00 per share, it is expected to be classified as a penny stock. The SEC rules regarding penny stocks may have the effect of reducing trading activity in our shares, making it more difficult for investors to sell. Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

- make a special written suitability determination for the purchaser;
- receive the purchaser's written agreement to a transaction prior to sale;
- provide the purchaser with risk disclosure documents which identify certain risks associated with investing in penny stocks and which describe the market for these penny stocks as well as a purchaser's legal remedies;
- obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has received the required risk disclosure document before a transaction in a penny stock can be completed; and
- give bid and offer quotations and broker and salesperson compensation information to the customer orally or in writing before or with the confirmation.

These rules make it more difficult for broker-dealers to effectuate customer transactions and trading activity in our securities and may result in a lower trading volume of our common stock and lower trading prices.





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***Our Common Stock may be thinly traded.***

There is a minimal public market for our Common Stock. We cannot be certain more of a public market for our Common Stock will develop, or if developed, that it will be sustained. Our Common Stock will likely be thinly traded compared to larger more widely known companies. We cannot predict the extent to which an active public market for our Common Stock will develop or be sustained at any time in the future. If we are unable to develop or sustain a market for our Common Stock, investors may be unable to sell the Common Stock they own, and may lose the entire value of their investment.

***Securities analysts may elect not to report on our Common Stock or may issue negative reports that adversely affect the stock price.***

At this time, no securities analysts provide research coverage of our Common Stock, and securities analysts may elect not to provide such coverage in the future. Rules mandated by the Sarbanes-Oxley Act and a global settlement reached in 2003 among the SEC, other regulatory agencies, and a number of investment banks led to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms are required to contract with independent financial analysts for their stock research. It may remain difficult for a company such as ours, with a smaller market capitalization, to attract independent financial analysts that will cover our Common Stock. If securities analysts do not cover our Common Stock, the lack of research coverage may adversely affect its actual and potential market price. The trading market for our Common Stock may be affected in part by the research and reports that industry or financial analysts publish about its business. If one or more analysts elect to cover us and then downgrade the stock, the stock price would likely decline rapidly. If one or more of these analysts cease coverage of us, we could lose visibility in the market, which in turn could cause our stock price to decline. This could have a negative effect on the market price of our shares.

***We do not intend to pay cash dividends.***

We have never declared or paid cash dividends on our capital stock. We currently expect to use available funds and any future earnings in the development, operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, the terms of any future debt or credit facility we may obtain may preclude us from paying any dividends. As a result, capital appreciation, if any, of our Common Stock will be an investor's only source of potential gain from our Common Stock for the foreseeable future.

***Shareholders may experience significant dilution if future equity offerings are used to fund operations or acquire complementary businesses.***

If future operations or acquisitions are financed through the issuance of equity securities, shareholders could experience significant dilution. In addition, securities issued in connection with future financing activities or potential acquisitions may have rights and preferences senior to the rights and preferences of our Common Stock. The issuance of shares of our Common Stock upon the exercise of options may result in dilution to our shareholders.

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*We may become involved in securities class action litigation that could divert management's attention and harm its business.*

The stock market in general and the stocks of medical device companies in particular have experienced extreme price and volume fluctuations. These fluctuations have often been unrelated or disproportionate to the operating performance of the companies involved. If these fluctuations occur in the future, the market price of our shares could fall regardless of its operating performance. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has been brought against that company. If the market price or volume of our shares suffers extreme fluctuations, then we may become involved in this type of litigation which would be expensive and divert management's attention and resources from managing the business.

*Anti-takeover provisions in our organizational documents may discourage or prevent a change of control, even if an acquisition would be beneficial to shareholders, which could affect our share price adversely and prevent attempts by shareholders to replace or remove current management*

Our Articles of Incorporation and Bylaws contain provisions that could delay or prevent a change of control of our company or its Board of Directors that shareholders might consider favorable. Some of these provisions include:

- authorizing the issuance of preferred stock which can be created and issued by the Board of Directors without prior common stock shareholder approval, with rights senior to those of the common stock;
- restricting persons who may call shareholder meetings; and
- allowing the Board to fill vacancies and to fix the number of directors.

**Item 1B. Unresolved Staff Comments**

None

**Item 2. Properties**

Our corporate headquarters are located in Marietta, Georgia where we lease approximately 12,200 square feet of office, laboratory and manufacturing space. We lease approximately 5,000 square feet in Tampa, Florida, which primarily consists of laboratory (2,000 feet) and manufacturing (3,000 feet) space. We believe these facilities are adequate for our current activities but expect to lease additional space in conjunction with executing our business plan.

**Item 3. Legal Proceedings**

None

**Item 4. (Removed and Reserved)**

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities**

Our Common Stock was approved for quotation on the OTC Bulletin Board on July 19, 2007. Only a limited number of shares were traded after the approval of the quotation in July 2007. The Common Stock was traded with the trading symbol of AYXC.

Our common stock began trading under the symbol MDXG on April 2, 2008. The following table sets forth the high and low bid prices on the OTC Bulletin Board for our common stock, based on information provided from OTC Bulletin Board. These quotations reflect inter-dealer prices, without retail mark-up, mark-down, or commission and may not necessarily represent actual transactions.

	High*	Low*
Year Ended December 31, 2010		
First Quarter	\$ 1.75	\$ .75
Second Quarter	1.55	1.00
Third Quarter	1.48	0.99
Fourth Quarter	1.35	0.80
Year Ended December 31, 2009		
First Quarter	\$ 4.40	\$ .40
Second Quarter	.75	.40
Third Quarter	.75	.42
Fourth Quarter	.89	.60

\* Adjusted to reflect the reverse stock split effective on April 2, 2008.

Based upon information supplied from our transfer agent, there were approximately 750 shareholders of record of our Common Stock as of March 15, 2011.

We have not paid any cash dividends on our Common Stock since our formation and do not intend to do so in the future.

To facilitate trading in the Company's shares, the Board is considering applying for a listing on a national exchange. If the Board does determine to pursue listing on a national exchange, the Company may consider implementing a reverse split of its Common Stock.

**Unregistered Sales of Equity Securities and Use of Proceeds**

As reported in Note 7 Common Stock Placements in our consolidated financial statements as of and for the twelve months ended December 31, 2010, from January 1, 2011, through March 18, 2011, the Company sold an additional 1,088,775 shares of Common Stock and issued an additional 544,388 warrants and received cash proceeds of \$1,088,775. See Notes to Consolidated Financial Statements for the terms of the Warrants. These sales were made in conjunction with the Company's most recent private placement which commenced in October 2010 (October 2010 Private Placement).

The Company relied on Section 4(2) of the Securities Act of 1933 (the Securities Act) and Rule 506 of Regulation D under the Securities Act, as amended, to issue the securities described above because they were offered to accredited investors and a limited number of unaccredited investors who purchased for investment in transactions that did not involve a general solicitation.

Form 10-Q for the nine months ended September 30, 2010 filed November 15, 2010 and Form D dated November 29, 2010, also provide information related to unregistered sales of equity securities during the twelve months ended December 31, 2010.

We did not repurchase any shares during the last three months of 2010 and currently have no share repurchase plans or programs.



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**Item 6. Selected Financial Data**

Not applicable.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

You should read the following discussion and analysis of financial condition and results of operations, together with the financial statements and the related notes appearing at the end of this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the Risk Factors section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

The discussion and analysis of our financial conditions and results of operations are based on the Company's financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires making estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue, if any, and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

**Overview**

MiMedx Group, Inc. ( MiMedx Group ) is an integrated developer, manufacturer and marketer of patent-protected biomaterial-based products, headquartered in Marietta, Georgia. We operate in one business segment, Biomaterials. MiMedx Group is emerging from a development-focused start-up company into a fully integrated operating company with the expertise to capitalize on its science and technology and the capacity to generate sales growth and profitability.

Prior to the 4<sup>th</sup> quarter of 2009, the Company explored business strategies through our three development units, MiMedx, SpineMedica and Level Orthopedics. After the sale of the Level assets and a thorough review of the strategic direction of the Company, management made the decision in late 2009 to consolidate the organizational structure. Instead of independent development teams and manufacturing locations, we have integrated development teams and all manufacturing has been consolidated into one site. Our Tampa, Florida location focuses on research and early stage product and process development. Our Marietta, Georgia, location, will houses our corporate headquarters and our development and sales teams, as well as all manufacturing and distribution operations.

Our initial business strategy was to identify and acquire innovative new medical products and technologies, focused initially on the musculoskeletal market, as well as novel medical instrumentation and surgical techniques. We subsequently refined our strategy to specialize in proprietary biomaterial technologies that can be transformed into unique medical devices that fill an unmet or underserved clinical need. Our HydroFix hydrogel technology and our CollaFix collagen fiber technology are proprietary platforms that can serve as the basis for medical devices in various orthopedic and orthobiologic applications, such as spine, sports medicine, and trauma. We also have identified multiple product opportunities in general surgery, drug delivery, wound management and cardiac markets among others.

Our plan is to focus our internal commercialization efforts relative to our HydroFix<sup>TM</sup> and CollaFix<sup>TM</sup> materials on orthopedics and orthobiologic applications. As appropriate, we may partner with large, established companies in the general surgery, drug delivery, wound management, cardiac and other markets. Initial conversations with such external relationships have been initiated, but they will take time to develop.

We have organized an advisory panel of leading physicians to provide insight into our primary fields of interest for new products and technology, as well as guidance and advice with respect to ongoing product development programs.



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Our core focus is on near-term opportunities for each of our technologies, advancing them through the regulatory process, establishing reliable and cost-effective manufacturing, and establishing an effective distribution system. To implement our business plan and generate revenue from other sources, we must develop products and obtain regulatory clearances or approvals for those products in many jurisdictions. In 2010, we received two HydroFix CE Marks (European approval). The first was granted in February 2010 and is classified as a post-surgical adhesion inhibiting barrier and is used in specific spine surgeries. We recorded our first revenue for this product in the first quarter of 2010. In December 2010, we received a second CE mark for HydroFix Spine Shield for use in contact with the central circulatory system and the central nervous system. There was no revenue recorded in 2010 for this indication due to the fact that it was granted in late December.

**Critical Accounting Policies**

We believe that of our significant accounting policies, which are described in Note 2 to our financial statements appearing elsewhere in this report, the following accounting policies involve a greater degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of operations.

*Goodwill and intangible assets:*

Intangible assets include licensing rights and are accounted for based on FASB Accounting Standards Codification 350, Intangibles Goodwill and Other (ASC 350), previously referred to as Financial Accounting Standard Statement No. 142 Goodwill and Other Intangible Assets. In that regard, goodwill is not amortized but is tested at least annually for impairment, or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with finite useful lives are amortized using the straight-line method over a period of ten years, the remaining term of the patents underlying the licensing rights (considered to be the remaining useful life of the license). Significant judgments are involved in estimating future cash flows used to support the carrying value of goodwill and indefinite lived intangible assets.

*Impairment of long-lived assets:*

We evaluate the recoverability of our long-lived assets (finite lived intangible asset and property and equipment) whenever adverse events or changes in business climate indicate that the expected undiscounted future cash flows from the related assets may be less than previously anticipated. If the net book value of the related assets exceeds the expected undiscounted future cash flows of the assets, the carrying amount will be reduced to the present value of their expected future cash flows and an impairment loss would be recognized. Factors that may cause long-lived asset impairment include negative industry or economic trends and significant underperformance relative to historical or projected future operating results.

*Share-based compensation:*

We follow the provisions of FASB Accounting Standards Codification 718, Compensation Stock Compensation (ASC 718), previously referred to as Statement of Financial Accounting Standards No. 123R Share-based Payments which requires the measurement and recognition of compensation expense for all share-based payment awards either modified or granted to employees and directors based upon estimated fair values. The Black-Scholes-Merton option-pricing model, consistent with the provisions of ASC 718, was used to determine the fair value of each option granted. Option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. The Company uses projected volatility rates, which are based upon historical volatility rates, trended into future years. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of the Company's options.



**Table of Contents****Recently Adopted Accounting Pronouncements**

In June 2009, the FASB issued Accounting Standards Update No. 2009-01 ( ASU 2009-01 ), which establishes the FASB Accounting Standards Codification as the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. The Company adopted ASU 2009-01 during the three months ended September 30, 2009, and its adoption did not have any impact on the Company's consolidated financial statements. In August 2009, the FASB issued Accounting Standards Update No. 2009-05 ( ASU 2009-05 ), which clarified how to measure the fair value of liabilities in circumstances when a quoted price in an active market for the identical liability is not available. ASU 2009-05 is effective for the first reporting period beginning after the issuance of this standard. The Company adopted ASU 2009-05, and its adoption did not have an impact on its consolidated financial statements. In October 2009, the FASB issued Accounting Standards Update No. 2009-13 ( ASU 2009-13 ), which addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified beginning in fiscal years on or after June 15, 2010. Early adoption is permitted. The Company does not expect the adoption of this standard to have any effect on its financial statements until or unless it enters into agreements covered by this standard.

In January 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2010-06 to Topic 820 *Fair Value measurements and Disclosures*. This update provided requirements of new disclosures of significant transfers and also clarified existing disclosures around the level of disaggregation of each class of assets and liabilities, and about fair value inputs and valuation techniques. This update was effective for interim and annual reporting periods beginning after December 15, 2009. Adoption of this update did not have a material impact on our financial statements.

In February 2010, the FASB issued ASU 2010-09 to Topic 855 *Subsequent Events*, to amend certain recognition and disclosure requirements related to subsequent events. The new guidance clarifies that management must evaluate, as of each reporting period, events or transactions that occur after the balance sheet date through the date that the financial statements are issued. Management must perform its assessment for both interim and annual financial reporting periods. This update also exempts SEC filers from disclosing the date through which subsequent events have been evaluated. Adoption of this update did not have a material impact on our financial statements.

**Recently Issued Accounting Pronouncements Not Yet Adopted**

In December 2010, the FASB issued ASU 2010-28 to Topic 350 *Intangibles - Goodwill and Other: When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts*. The amendments to the Codification in this update modify Step 1 of the goodwill impairment test for reporting units with zero or negative carrying amounts. For those reporting units, an entity is required to perform Step 2 of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. Goodwill of a reporting unit is required to be tested for impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. This update is effective starting in the first quarter of 2011 with early adoption not permitted. Adoption of this update is not expected to have a material impact on our financial statements.

In December 2010, the FASB issued ASU 2010-29 to Topic 805 *Business Combinations: Disclosure of Supplementary Pro Forma Information for Business Combinations*. The amendments to the Codification in this ASU apply to any public entity that enters into business combination that are material on an individual or aggregate basis and specify that the entity presents comparative financial statements, the entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. The update also expands the supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. The update is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning in January 2011 with early adoption permitted. We plan to adopt this update for all acquisitions completed beginning in 2011 and provide the appropriate disclosures.



**Table of Contents****Results of Operations for the year ended December 31, 2010, compared to the 9 months ended December 31, 2009**

We are comparing the year ended December 31, 2010 to the nine months ended December 31, 2009 as the Company changed its fiscal year end to December 31 at December 31, 2009. Therefore, 2010 results reflect an inherently longer operating period and is a primary factor in increases in costs when comparing the two periods. Also in 2010, MiMedx emerged from being a development stage company into an operating company as we recorded our first significant revenue, as noted below.

***Net Sales***

Net sales increased from \$800 in 2009 to \$789,000 in 2010. Product sales were \$544,000 comprised primarily of sales of our HydroFix Vaso Shield products in the U.S. and HydroFix Spine Shield products outside the U.S. Other revenue included \$245,000 for the Qualifying Therapeutic Discovery Project grant from the U.S. Government. Net sales were lower than plan due primarily to delays in regulatory clearances of products in both the HydroFix and CollaFix product platforms.

***Cost of Product Sold***

Cost of products sold was \$1,720,000 representing the manufacturing of initial product sales and the costs associated with the ramp up of our manufacturing operations including the required quality assurance organization. As of December 31, 2010, we had 9 employees devoted to manufacturing and quality assurance activities. Personnel costs represent approximately 68.5% of total manufacturing and quality assurance spending. Idle facility expense, excessive spoilage, extra freight, and handling costs are included in cost of product sales and are not capitalized into inventories. Allocation of fixed production overheads is based on the normal capacity of production facilities. We anticipate spending in the area of manufacturing and quality assurance to increase in support of production rate increases.

***Research and Development Expenses***

Research and development expenses during the year ended December 31, 2010, increased approximately \$163,000 to \$2,753,000 compared to \$2,590,000 for the nine months ended December 31, 2009. Our research and development expenses consist primarily of internal personnel costs, fees paid to external consultants, and supplies and instruments used in our laboratories. As of December 31, 2010, we employed 12 employees devoted to research and development, validation of our manufacturing processes, and the manufacturing of prototype devices. As of December 31, 2009, we had 28 employees devoted to these efforts. Personnel costs represent approximately 54.7% of total research and development expenses during the year ended December 31, 2010 as compared to 55.5% for the nine months ended December 31, 2009. Fees paid to external consultants and supplies and instruments used in our laboratories represent approximately 6.0% and 4.6% , respectively, of research and development expenses during the year ended December 31, 2010 as compared to 32.8% and 11.7% for the nine months ended December 31, 2009. Spending on animal studies increased 75.1% in support of our product release roadmap. We anticipate our spending in the area of research and development in the foreseeable future to continue at comparable current levels as we progress our technologies through additional testing and validation in order to obtain clearance or approval from the FDA to market our technologies.

***Selling, General and Administrative Expenses***

Selling, General and Administrative expenses for the year ended December 31, 2010, increased approximately \$3,384,000 to \$6,848,000 compared to \$3,463,000 for the nine months ended December 31, 2009. Included in our selling general and administrative expenses for the nine months ended December 31, 2009, is a \$585,000 gain on settlement of accounts payable on expenses recorded in the prior fiscal year. Excluding the gain on settlement of payables our selling, general and administrative expenses increased \$2,778,000 compared to the nine months ended December 31, 2009. The increase in selling, general and administrative expenses includes an investment of \$1,061,000 in a global sales and distribution organization to support our growth objectives. The spending increase also includes \$690,000 in additional share based compensation expense as well as \$277,000 in increased depreciation and amortization expense. Selling, General and administrative expenses consist of personnel costs, professional fees, facilities costs and other administrative costs. During the year ended December 31, 2010, salaries and benefits, excluding stock-based compensation, totaled \$2,099,000 compared to \$1,325,000 for the nine months ended December 31, 2009. The increase primarily relates to the investment in sales and product management personnel

whose responsibilities include building a global network of third party sales representatives and distributors as well as the management of our two product platforms. As of December 31, 2010, we employed 11 personnel in our selling, general and administrative organization as compared to 12 as of December 31, 2009.

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During the year ended December 31, 2010, we recorded approximately \$444,000 in depreciation expense and approximately \$668,000 in amortization expense as compared to amounts approximating \$338,000 and \$497,000, respectively, for the nine months ended December 31, 2009. We depreciate our assets on a straight-line basis, principally over five to seven years and amortize our intangible assets over a period of ten years, which we believe represents the estimated useful lives of the patents underlying the licensing rights and intellectual property. We do not amortize goodwill but at least annually we test goodwill for impairment and periodically evaluate other intangibles for impairment based on events or changes in circumstances as they occur.

***Gain on Sale of Assets***

During the last three months of 2009, we sold our upper extremities technology, which we referred to as our Level Orthopedics development unit, in two separate transactions. In total we received cash proceeds of \$360,000 and a \$100,000 secured promissory note for these assets, and recognized a gain of approximately \$281,000. Additionally, we may receive up to \$630,000 in future royalty payments in conjunction with one of the transactions, but due to the contingent nature of the royalty payments we did not recognize these potential payments in calculating our gain on sale. As of December 31, 2010, we have not received any royalty payments related to this transaction. As of December 31, 2010 there is \$40,000 in notes receivable included on our balance sheet related to this transaction. We anticipate spending in the area of general and administrative expenses in the foreseeable future to continue at comparable current levels.

***Other Income / (Expense)***

In 2010, we recorded \$288,000 of financing expense related to four (4) Hybrid Debt Instruments issued at various times in the fourth quarter of 2010. We also recorded approximately \$593,000 in interest expense related to the 3% Convertible Notes issued in 2009. (See Footnote 6 in the Notes to Consolidated Financial Statements).

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***Off-Balance Sheet Arrangements***

We have no off-balance sheet arrangements.

***Liquidity and Capital Resources***

The Company emerged from being a development stage company in 2010. Planned principal operations have commenced, but the revenue has not been significant enough to fund ongoing operations. The Company's cash requirements for the twelve months ended December 31, 2010 arose out of general working capital needs. The Company funded its cash requirements primarily through a combination of debt and equity financings with a lesser amount derived from company revenue. As of December 31, 2010, the Company had approximately \$1,341,000 of cash and cash equivalents. Through March 15, 2011, the Company received an additional \$1,089,000 of proceeds related to sales of its common stock and warrants. On March 18, 2011, the Board approved an agreement between the Company and its CEO whereby the CEO will provide the Company with a line of credit of up to \$3.6 million to fund ongoing operating cash requirements. The Company believes that its anticipated cash from operations, existing cash and cash equivalents and the aforementioned line of credit will enable the Company to meet its operational liquidity needs for the next twelve months.

***Inflation***

We do not believe that the rate of inflation has had a material effect on our operating results. However, inflation could adversely affect our future operating results.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

The Company's business is anticipated to be directly dependent on foreign operations as the Company's sales to customers outside the U.S. become significant. A portion of the Company's total revenue are anticipated to be dependent on selling to distributors outside the U.S., some of which will be invoiced in foreign currencies, primarily the EURO. There is also risk related to the changes in foreign currency exchange rates as it relates to sales operating expenses paid in EUROS. We are currently considering taking affirmative steps to hedge the risk of fluctuations in foreign currency exchange rates as revenue continues to increase. We do not expect our financial position, results of operations or cash flows to be materially impacted due to a sudden change in foreign currency exchange rates fluctuations relative to the U.S. Dollar over the next six months.

Our exposure to market risk relates to our cash and investments.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest our excess cash in debt instruments of the U.S. Government and its agencies, bank obligations, repurchase agreements and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than three months.

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**Item 8. Financial Statements and Supplementary Data  
Index to Financial Statements**

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<u>Consolidated Balance Sheets As of December 31, 2010, and December 31, 2009</u>	42
<u>Consolidated Statements of Operations For the year ended December 31, 2010, and the nine months ended December 31, 2009</u>	43
<u>Consolidated Statements of Stockholders Equity (Deficit) and Comprehensive Income (Loss) For the year ended December 31, 2010, and the nine months ended December 31, 2009</u>	45
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Report of Independent Registered Public Accounting Firm  
Board of Directors  
MiMedx Group, Inc.

We have audited the accompanying consolidated balance sheets of MiMedx Group, Inc. and subsidiaries as of December 2010 and 2009, and the related consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2010, and for the nine months ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States of America). The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above, present fairly, in all material respects, the consolidated financial position of MiMedx Group, Inc. and subsidiaries as of December 31, 2010 and 2009, and the consolidated results of their operations and their cash flows for the year ended December 31, 2010 and for the nine months ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

/s/ Cherry, Bekaert & Holland, L.L.P.

Cherry, Bekaert & Holland, L.L.P.

Atlanta, Georgia

March 31, 2011



**Table of Contents**MIMEDX GROUP, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2010	2009
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,340,922	\$ 2,653,537
Accounts receivable, net	162,376	
Inventory	111,554	30,920
Prepaid expenses and other current assets	90,946	121,277
Total current assets	1,705,798	2,805,734
Property and equipment, net of accumulated depreciation of \$1,392,704 and \$948,445, respectively	756,956	1,049,597
Goodwill	857,597	857,597
Intangible assets, net of accumulated amortization of \$2,132,606 and \$1,464,674, respectively	3,929,394	4,597,326
Deferred financing costs		192,627
Deposits and other long term assets	102,500	189,202
Total assets	\$ 7,352,245	\$ 9,692,083
 <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 848,285	\$ 629,349
Short-term convertible notes, plus accrued interest of \$3,432	403,432	
Total current liabilities	1,251,717	629,349
Long-term convertible debt, face value \$3,472,000, less unamortized discount of \$550,748 and including accrued interest of \$69,604		2,990,856
Total liabilities	1,251,717	3,620,205
Commitments and contingency (Note 14)		
Stockholders equity:		
Preferred stock; \$.001 par value; 5,000,000 shares authorized and 0 shares issued and outstanding		
Common stock; \$.001 par value; 100,000,000 shares authorized; 64,331,910 and 50,002,887 shares issued and outstanding, respectively	64,382	50,003
Additional paid-in capital	57,888,506	46,454,482

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Treasury stock (50,000 shares at cost)	(25,000)	(25,000)
Accumulated deficit	(51,827,360)	(40,407,607)
Total stockholders' equity	6,100,528	6,071,878
Total liabilities and stockholders' equity	\$ 7,352,245	\$ 9,692,083

See notes to consolidated financial statements

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MIMEDX GROUP, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31, 2010	Nine Months Ended December 31, 2009
<b>REVENUES:</b>		
Net sales	\$ 544,155	\$ 800
Grant Revenue	244,719	\$
Total revenue	788,874	800
<b>OPERATING COSTS AND EXPENSES:</b>		
Cost of products sold	1,720,063	240
Research and development expenses	2,753,331	2,590,227
Selling, General and Administrative expenses	6,848,135	3,463,303
Gain on sale of assets		(280,868)
<b>LOSS FROM OPERATIONS</b>	<b>(10,532,655)</b>	<b>(5,772,102)</b>
<b>OTHER INCOME (EXPENSE)</b>		
Financing expense associated with issuance of common stock for registration rights waivers		(1,305,100)
Financing expense associated with warrants issued in connection with convertible promissory note	(287,449)	(975,833)
Interest (expense) income, net	(599,649)	(242,634)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(11,419,753)</b>	<b>(8,295,669)</b>
Income taxes		
<b>NET LOSS</b>	<b>(11,419,753)</b>	<b>(8,295,669)</b>
Net loss per common share		
Basic and diluted	\$ (0.19)	\$ (0.20)
Shares used in computing net loss per common share		
Basic and diluted	59,138,357	41,365,513

See notes to consolidated financial statements



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MIMEDX GROUP, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2010	Nine Months Ended December 31, 2009
Cash flows from operating activities:		
Net loss	\$ (11,419,753)	\$ (8,295,669)
Adjustments to reconcile net loss to net cash flows from operating activities, net of effects of acquisition:		
Gain on settlement of payables		(584,969)
(Gain)/loss on sale of assets		(280,868)
Depreciation	444,259	337,909
Amortization of intangible assets	667,932	497,211
Amortization of debt discount and deferred financing costs	599,001	169,739
Employee share-based compensation expense	996,307	363,457
Other share-based compensation expense	174,354	117,689
Financing expense associated with issuance of common stock for waivers of registration rights		1,305,100
Financing expense associated with warrants issued in connection with convertible promissory note	287,448	975,833
Modifications of options and purchase of treasury stock		48,000
Increase (decrease) in cash resulting from changes in:		
Accounts receivable, net	(162,376)	
Inventory	(80,634)	(30,920)
Prepaid expenses and other current assets	30,331	21,676
Other assets	86,702	
Accounts payable and accrued expenses	218,936	(240,468)
<b>Net cash flows from operating activities</b>	<b>(8,157,494)</b>	<b>(5,596,280)</b>
Cash flows from investing activities:		
Purchase of equipment	(151,617)	(11,610)
Proceeds from sale of assets		360,250
Cash paid in conjunction with sales of assets		(86,332)
<b>Net cash flows from investing activities</b>	<b>(151,617)</b>	<b>262,308</b>
Cash flows from financing activities:		
Proceeds from convertible debt offering		3,472,000
Proceeds from bridge loan	500,000	
Proceeds from convertible promissory note		500,000
Repayment of convertible promissory note		(500,000)
Proceeds from sale of common stock and warrants and common stock with registration rights, net	3,122,020	4,618,719
Proceeds from exercise of stock options	155,126	2

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Net proceeds from exercise of warrants	3,219,349	
Offering costs paid in connection with convertible debt offering		(138,040)
Net cash flows from financing activities	6,996,495	7,952,681
Net change in cash	(1,312,615)	2,618,709
Cash, beginning of period	2,653,537	34,828
Cash, end of period	\$ 1,340,922	\$ 2,653,537
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 8,330	\$ 4,745
Cash paid for income taxes	\$	\$

**Supplemental disclosure of non-cash financing activity:**

**During the year ended December 31, 2010:**

- \* the Company issued 500,000 warrants in conjunction with the issuance of Hybrid Debt instruments valued at \$141,974.
- \* the Company recognized a beneficial conversion feature valued at \$145,474 related to the Hybrid Debt instruments.
- \* the Company recognized the amortization of debt discount and deferred financing costs related to the conversion of convertible debt in the amount of \$599,001.

**During the nine months ended December 31, 2009:**

- \* the Company recognized amortization of a debt discount and deferred interest of \$169,739 in conjunction with our convertible debt offering.
- \* the Company issued 315,520 warrants to purchase common stock, valued at \$98,574
- \* the Company issued 100,000 shares valued at \$42,000 for costs associated with its private placement sale of common stock and warrants, 162,750 shares valued at \$81,375 for accrued directors fees, and 187,644 shares valued at \$93,822 for accrued executive compensation.
- \* the Company reclassified 1,905,000 shares with registration rights valued at \$3,761,250 to equity as the result of the termination of such rights, and issued 2,490,000 shares valued at \$1,305,100 as settlement of the waived rights (Note7).
- \* the Company issued 100,000 shares of common stock valued at \$71,000 for intellectual property upon achieving certain milestones (Note 5).
- \* the Company issued 975,833 warrants valued at \$975,833 in conjunction with a convertible promissory note.
- \* the Company received a \$100,000 3% Secured Promissory Note in conjunction with its sale of intellectual property (Note 5)

See notes to consolidated financial statements

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MIMEDX GROUP, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
Balances, March 31, 2009	37,339,628	37,340	34,230,824		(32,111,938)	2,156,226
Employee share-based compensation expense			363,457			363,457
Other share-based compensation expense			117,689			117,689
Beneficial conversion feature recognized on convertible debt			676,500			676,500
Warrants issued to placement agents in conjunction with convertible debt			98,574			98,574
Exercise of stock options	20,000	20	(18)			2
Common stock issued for waivers of registration rights	2,490,000	2,490	1,302,610			1,305,100
Reclassification of common stock with registration rights	1,905,000	1,905	3,759,345			3,761,250
Common stock issued for accrued directors fees	162,750	163	81,212			81,375
Common stock issued for accrued executive compensation	187,644	187	93,635			93,822
Common Stock issued in connection with purchase of license agreement	100,000	100	70,900			71,000
Sale of common stock and warrants (net of \$42,000 of offering costs)	7,697,865	7,698	4,569,021			4,576,719
Common stock issued for services in conjunction with private placement	100,000	100	41,900			42,000
			975,833			975,833

Warrants issued in conjunction with convertible promissory note						
Modification of stock options and purchase of treasury stock			73,000	(25,000)		48,000
Net loss for the period					(8,295,669)	(8,295,669)
Balances, December 31, 2009	50,002,887	\$ 50,003	\$ 46,454,482	\$ (25,000)	\$ (40,407,607)	\$ 6,071,878
Employee share-based compensation expense			996,307			996,307
Other share-based compensation expense			174,354			174,354
Beneficial conversion feature recognized on convertible debt			287,448			287,448
Sale of common stock and warrants (net of \$67,980 of offering costs)	3,713,433	3,713	3,118,307			3,122,020
Exercise of stock options	210,250	211	154,915			155,126
Exercise of warrants	3,219,348	3,219	3,216,130			3,219,349
Shares issued in conjunction with conversion of convertible debt	7,235,992	7,236	3,486,563			3,493,799
Net loss for the year					(11,419,753)	(11,419,753)
Balances, December 31, 2010	64,381,910	\$ 64,382	\$ 57,888,506	\$ (25,000)	\$ (51,827,360)	\$ 6,100,528

See notes to consolidated financial statements



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MIMEDX GROUP, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2010

**1. Formation and nature of business:**

*Nature of business:*

Prior to the fiscal year ended December 31, 2010 MiMedx was considered a Development Stage Enterprise.

MiMedx, Inc. ( MiMedx ) was incorporated in Florida in 2006. MiMedx entered into and consummated an Agreement and Plan of Merger ( Merger Agreement ) with a publicly-traded Nevada Corporation, Alynx, Co. ( Alynx ), a public shell company, on February 8, 2008. As a result of this transaction, MiMedx shareholders owned approximately 97% of the outstanding shares, thus giving MiMedx substantial control.

Under U.S. generally accepted accounting principles ( GAAP ), MiMedx was deemed to be the accounting acquirer since the shareholders of MiMedx own a substantial majority of the issued and outstanding shares, and thus this reverse merger was accounted for as a capital transaction. The historical financial statements are a continuation of financial statements of the accounting acquirer and the capital structure of the consolidated enterprise is now different from that appearing in the historical financial statements of the accounting acquirer in earlier periods due to the recapitalization.

On March 31, 2008, MiMedx Group, Inc., a Florida Corporation, and Alynx merged. As a result of this transaction, MiMedx Group, Inc. became the surviving corporation. The Company refers to MiMedx Group, Inc. which is comprised of its two operating subsidiaries: MiMedx and SpineMedica, LLC.

MiMedx acquired a license for the use, adoption and development of certain core technologies developed at the Shriners Hospital for Children and the University of South Florida Research Foundation. This technology focuses on biomaterials for soft tissue repair, such as tendons, ligaments and cartilage, as well as other biomaterial-based products for numerous other medical applications. The development of the licensed technologies requires continued research and development and, ultimately, the approval of the U.S. Food and Drug Administration ( FDA ) and/or foreign regulatory authorities in order for the Company to be able to generate revenue from the sale of its products. This process is expected to take at least six months to one year, and there can be no assurance that the Company will be successful in its efforts to commercialize the licensed technology.

On July 23, 2007, MiMedx acquired SpineMedica Corp. through its wholly-owned subsidiary, SpineMedica, LLC ( SpineMedica ). SpineMedica Corp. was incorporated in the State of Florida on June 9, 2005 and its successor SpineMedica, LLC was incorporated in the State of Florida on June 27, 2007. SpineMedica has licensed the right to use Salubria®, or similar poly-vinyl alcohol ( PVA )-based biomaterials for certain applications within the body. SpineMedica also owns certain assets (equipment) for the production of products based on a PVA-based hydrogel, which is a water-based biomaterial that can be manufactured with a wide range of mechanical properties, including those that appear to closely mimic the mechanical and physical properties of natural, healthy human tissue.

The Company operates in one business segment, Biomaterials, which includes the design, manufacture, and marketing of products for the Orthopedics and Spine market categories.

**Table of Contents****2. Significant accounting policies:***Fiscal year:*

The current fiscal year is for the twelve months ended December 31, 2010. The prior year reported financials were for the nine months ended December 31, 2009 due to a change in fiscal year from March to December in 2009. The result of this change is that our reporting period for the current fiscal year is compared to the nine months ended December 31, 2009. The comparable amounts for the twelve months ended December 31, 2010 and 2009 (unaudited), respectively, are as follows:

	<b>Year ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Revenues	\$ 788,874	\$ 800
Loss from operations	<b>(10,532,658)</b>	(9,229,749)
Loss before income tax	<b>(11,419,756)</b>	(11,167,653)
Income tax		
Net loss	<b>(11,419,756)</b>	(11,167,653)
Net loss per common share	\$ (0.19)	\$ (0.28)

*Use of estimates:*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

*Principles of consolidation:*

The financial statements include the accounts of MiMedx Group, Inc. and its wholly-owned subsidiaries MiMedx and, SpineMedica. All significant inter-company balances and transactions have been eliminated.

*Concentrations of credit risk:*

The Company places its cash and cash equivalents on deposit with financial institutions in the United States. In October and November 2008 the Federal Deposit Insurance Corporation (FDIC) temporarily increased coverage to \$250,000 for substantially all depository accounts and temporarily provides unlimited coverage for certain qualifying and participating non-interest bearing transaction accounts. The increased coverage is scheduled to expire on December 31, 2013, at which time it is anticipated amounts insured by the FDIC will return to \$100,000. During the year, the Company from time to time may have had amounts on deposit in excess of the insured limits. As of December 31, 2010, the Company had cash and cash equivalents of approximately \$1,341,000 which exceeds these insured amounts.

*Cash and cash equivalents:*

Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less.

*Accounts Receivable*

Accounts receivable represent amounts due from customers for which revenue has been recognized. Generally, the Company does not require collateral or any other security to support its receivables.

The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing receivables. The Company determines the allowance based on factors such as historical collection experience, customer's current creditworthiness, customer concentration, age of accounts receivable balance and general economic conditions that may affect the customer's ability to pay. As of December 31, 2010, the Company has \$21,600 in the allowance for doubtful accounts. Actual customer collections could differ from estimates.

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*Inventories:*

Inventories at December 31, 2010 are valued at the lower of actual cost or market, using the first-in, first-out (FIFO) method. Work in process is calculated by estimating the number of units that will be successfully converted to finished goods, based upon a build-up in the stage of completion using estimated labor inputs for each stage and historical yields reduced by estimated usage for quality control testing. Idle facility expense, excessive spoilage, extra freight, and handling costs are expensed, as necessary, in cost of sales and are not capitalized into inventories. Allocation of fixed production overheads is based on the normal capacity of production facilities.

*Goodwill and intangible assets:*

Goodwill is tested at least annually for impairment, or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with finite useful lives are amortized using the straight-line method over a period of 10 years, the estimated term of the patents underlying the licensing rights and intellectual property. The estimated remaining useful life of the assets is approximately seven more years.

*Property and equipment:*

Property and equipment are recorded at cost and depreciated on a straight-line basis over their estimated useful lives, principally five to seven years. Leasehold improvements are depreciated on a straight-line basis over the lesser of the estimated useful lives or the life of the lease.

*Impairment of long-lived assets:*

The Company evaluates the recoverability of its long-lived assets (finite lived intangible assets and property and equipment) whenever adverse events or changes in business climate indicate that the expected undiscounted future cash flows from the related assets may be less than previously anticipated. If the net book value of the related assets exceeds the expected undiscounted future cash flows of the assets, the carrying amount would be reduced to the present value of their expected future cash flows and an impairment loss would be recognized. There has been no impairment losses in the periods presented.

*Revenue Recognition:*

The Company sells its products primarily through a combination of independent stocking distributors and representatives in the U.S. and independent distributors in international markets. The Company recognizes revenue when title to the goods and risk of loss transfers to customers, provided there are no material remaining performance obligations required of the Company or any matters of customer acceptance. In cases where the Company utilized distributors or ships product directly to the end user, it recognizes revenue upon shipment provided all revenue recognition criteria have been met. A portion of the Company's revenue is generated from inventory maintained at hospitals or with field representatives. For these products, revenue is recognized at the time the product has been used or implanted. The Company records estimated sales returns, discounts and allowances as a reduction of net sales in the same period revenue is recognized.

*Research and development costs:*

Research and development costs consist of direct and indirect costs associated with the development of the Company's technologies. These costs are expensed as incurred.

**Table of Contents***Income taxes:*

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that included the enactment date. Valuation allowances are recorded for deferred tax assets when the recoverability of such assets is not deemed more likely than not.

*Share-based compensation:*

The Company follows the provisions of ASC topic 718 Compensation Stock compensation which requires the use of the fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock or equity instruments (options and warrants). All awards are amortized on a straight-line basis over their vesting terms into Selling, General and Administrative Expenses in the consolidated Statements of Operations.

*Fair value of financial instruments:*

The carrying value of accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities. The fair value of our short term convertible debt approximates \$403,000 which represents the face value and accrued but unpaid interest at December 31, 2010.

*Net loss per share*

Basic net loss per common share is computed using the weighted-average number of common shares outstanding during the period.

For all periods presented, diluted net loss per share is the same as basic net loss per share, as the inclusion of equivalent shares from outstanding common stock options, warrants, convertible debt and preferred stock would be anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share for the fiscal year ended December 31, 2010 and the nine months ended December 31, 2009:

	Year ended December 31, 2010	Nine Months ended December 31, 2009
Net loss	\$ (11,419,753)	\$ (8,295,669)
Denominator for basic earnings per share weighted average shares	59,138,357	41,365,513
Effect of dilutive securities: Stock options and warrants outstanding <sup>(a)</sup>		
Denominator for diluted earnings per share weighted average shares adjusted for dilutive securities	59,138,357	41,365,513
Loss per common share basic and diluted	\$ (0.19)	\$ (0.20)

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- (a) Securities outstanding that were excluded from the computation, prior to the use of the treasury stock method, because they would have been anti-dilutive are as follows:

	Year ended December 31, <b>2010</b>	Nine Months ended December 31, <b>2009</b>
Outstanding Stock Options	8,257,650	6,182,500
Outstanding Warrants	6,003,924	6,991,371
Convertible Debt	403,432	6,944,000
	14,661,574	20,117,871

*Recently issued accounting pronouncements:*

In June 2009, the FASB issued Accounting Standards Update No. 2009-01 ( ASU 2009-01 ), which establishes the FASB Accounting Standards Codification as the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. The Company adopted ASU 2009-01 during the three months ended September 30, 2009, and its adoption did not have any impact on the Company's consolidated financial statements.

In August 2009, the FASB issued Accounting Standards Update No. 2009-05 ( ASU 2009-05 ), which clarified how to measure the fair value of liabilities in circumstances when a quoted price in an active market for the identical liability is not available. ASU 2009-05 is effective for the first reporting period beginning after the issuance of this standard. The Company adopted ASU 2009-05, and its adoption did not have an impact on its consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update No. 2009-13 ( ASU 2009-13 ), which addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified beginning in fiscal years on or after June 15, 2010. Early adoption is permitted. The Company does not expect the adoption of this standard to have any effect on its financial statements until or unless it enters into agreements covered by this standard.

In January 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2010-06 to Topic 820 *Fair Value measurements and Disclosures*. This update provided requirements of new disclosures of significant transfers and also clarified existing disclosures around the level of disaggregation of each class of assets and liabilities, and about fair value inputs and valuation techniques. This update was effective for interim and annual reporting periods beginning after December 15, 2009. Adoption of this update did not have a material impact on our financial statements.

In February 2010, the FASB issued ASU 2010-09 to Topic 855 *Subsequent Events*, to amend certain recognition and disclosure requirements related to subsequent events. The new guidance clarifies that management must evaluate, as of each reporting period, events or transactions that occur after the balance sheet date through the date that the financial statements are issued. Management must perform its assessment for both interim and annual financial reporting periods. This update also exempts SEC filers from disclosing the date through which subsequent events have been evaluated. Adoption of this update did not have a material impact on our financial statements.

**Recently Issued Accounting Pronouncements Not Yet Adopted**

In December 2010, the FASB issued ASU 2010-28 to Topic 350 *Intangibles - Goodwill and Other: When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts*. The amendments to the Codification in this update modify Step 1 of the goodwill impairment test for reporting units with

zero or negative carrying amounts. For those reporting units, an entity is required to perform Step 2 of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. Goodwill of a reporting unit is required to be tested for impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. This update is effective starting in the first quarter of 2011 with early adoption not permitted. Adoption of this update is not expected to have a material impact on our financial statements.

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In December 2010, the FASB issued ASU 2010-29 to Topic 805 *Business Combinations: Disclosure of Supplementary Pro Forma Information for Business Combinations*. The amendments to the Codification in this ASU apply to any public entity that enters into business combination that are material on an individual or aggregate basis and specify that the entity presents comparative financial statements, the entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. The update also expands the supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. The update is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning in January 2011 with early adoption permitted. We plan to adopt this update for all acquisitions completed beginning in 2011 and provide the appropriate disclosures.

**3. Liquidity and management s plans:**

The Company emerged from being a development stage company in 2010. Planned principal operations have commenced, but the revenue has not been significant enough to fund ongoing operations. The Company s cash requirements for the twelve months ended December 31, 2010 arose out of general working capital needs. The Company funded its cash requirements primarily through a combination of debt and equity financings with a lesser amount derived from company revenue. As of December 31, 2010, the Company had approximately \$1,341,000 of cash and cash equivalents. Through March 15, 2011, the Company received an additional \$1,089,000 of proceeds related to sales of its common stock and warrants. On March 18, 2011, the Board approved an agreement between the Company and its CEO whereby the CEO will provide the Company with a line of credit of up to \$3.6 million to fund ongoing operating cash requirements. The Company believes that its anticipated cash from operations, existing cash and cash equivalents and the aforementioned line of credit will enable the Company to meet its operational liquidity needs for the next twelve months.

**4. Property and equipment:**

Property and equipment consist of the following at:

	December 31,	
	2010	2009
Leasehold improvements	\$ 793,900	\$ 793,899
Furniture and equipment	1,355,760	1,204,143
	2,149,660	1,998,042
Less accumulated depreciation	(1,392,704)	(948,445)
	\$ 756,956	\$ 1,049,597

**Table of Contents****5. Intangible assets and royalty agreement:**

Intangible assets activity is summarized as follows:

	Weighted Average Amortization Lives	December 31, 2010			December 31, 2009		
		Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
License-Shriners Hsp for Children & USF Research License	10 years	\$ 996,000	(388,433)	607,567	\$ 996,000	\$ (288,833)	\$ 707,167
SaluMedica LLC Spine Repair License Polyvinyl	10 years	2,399,000	(1,017,557)	1,381,443	2,399,000	(721,541)	1,677,459
Alco holCryogel	10 years	2,667,000	(726,616)	1,940,384	2,667,000	(454,300)	2,212,700
Total intangible assets		\$ 6,062,000	\$ (2,132,606)	\$ 3,929,394	\$ 6,062,000	\$ (1,464,674)	\$ 4,597,326

- (a) On January 29, 2007, the Company acquired a license from Shriners Hospitals for Children and University of South Florida Research Foundation, Inc. which is further discussed in Note 1. The acquisition price of this license was a one-time fee of \$100,000 and 1,120,000 shares of common stock valued at \$896,000 (based upon the estimated fair value of the common stock on the transaction date). Within thirty days after the receipt by the Company of approval by the FDA allowing the sale of the first licensed product, the Company is required to pay an additional \$200,000 to the licensor. This amount is not recorded as a liability as of December 31, 2009 or 2010, based on its contingent nature. The Company will also be required to pay a royalty of 3% on all commercial sales revenue of the licensed products.
- (b) License from SaluMedica, LLC (SaluMedica) for the use of certain developed technologies related to spine repair. This license was acquired through the acquisition of SpineMedica Corp.
- (c) On March 31, 2008, the Company entered into a license agreement for the use of certain developed technologies related to surgical sheets made of polyvinyl alcohol cryogel. The acquisition price of the asset was 400,000 shares of common stock valued at \$2,596,000 (based upon the closing price of the common stock on the transaction date). The agreement also provides for the issuance of an additional 600,000 shares upon the Company meeting certain milestones related to future sales. On December 31, 2009 the Company completed the sale of its first commercial product and met its first milestone under this agreement. As a result the Company issued 100,000 shares of common stock to the licensor valued at \$71,000. At December 31, 2009 or 2010, there are no additional amounts accrued for this obligation due to its contingent nature.

Expected future amortization of intangible assets is as follows:

**12-month period ended December 31,**

2011	\$ 667,932
2012	667,932
2013	667,932
2014	667,932
2015	561,694



Thereafter	695,971
	\$ 3,929,394

**6. Debt:***3% Convertible Senior Secured Promissory Notes:*

In April 2009, the Company commenced a private placement to sell 3% Convertible Senior Secured Promissory Notes (the Senior Notes ) to accredited investors. The Company completed the offering on June 17, 2009, and received aggregate proceeds of \$3,472,000, representing the face value of the Senior Notes. The aggregate proceeds include \$250,000 of Senior Notes sold to the Chairman of the Board, President and CEO, and \$150,000 of Senior Notes sold to one other director.

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In total, the Senior Notes are convertible into up to 6,944,000 shares of the Company's common stock at \$.50 per share (a) at any time upon the election of the holder of the Senior Notes; (b) automatically immediately prior to the closing of the sale of all or substantially all of the assets or more than 50% of the equity securities of the Company by way of a merger transaction or otherwise which would yield a price per share of not less than \$.50; or (c) at the election of the Company, at such time as the closing price per share of the Company's common stock (as reported by the OTCBB or on any national securities exchange on which the Company's shares may be listed) is not less than \$1.50 for at least 20 consecutive trading days in any period prior to the maturity date. If converted, the common stock will be available to be sold following satisfaction of the applicable conditions set forth in Rule 144. The Senior Notes mature in three years and earn interest at 3% per annum on the outstanding principal amount payable in cash on the maturity date or convertible into shares of common stock of the Company as provided for above. The Senior Notes are secured by a first priority lien on all of the assets, including intellectual property, of MiMedx, Inc., excluding, however, the membership interests in SpineMedica, LLC. The Senior Notes are junior in payment and lien priority to any bank debt of the Company in an amount not to exceed \$5,000,000 subsequently incurred by the Company.

The Company has evaluated the Senior Notes for accounting purposes under Generally Accepted Accounting Principles ( GAAP ) and has determined that the conversion feature meets the conventional-convertible exemption and, accordingly, bifurcation and fair-value measurement of the conversion feature is not required. We are required to re-evaluate this conclusion upon each financial statement closing date while the Senior Notes are outstanding. Notwithstanding, the Senior Notes were issued with a beneficial conversion feature, having an intrinsic value of approximately \$676,500. The intrinsic value of the beneficial conversion feature was determined by comparing the contracted conversion price to the fair value of the common stock on the date of the respective Senior Notes. A beneficial conversion feature only exists when the embedded conversion feature is in-the-money at the commitment date.

As a result of the beneficial conversion feature, the Senior Notes were recorded net of a discount of \$676,500 related to the beneficial conversion feature, which is recorded in paid-in capital, and the discount will be amortized through periodic charges to interest expense over the term of the Senior Notes using the effective interest method.

In conjunction with the offering, the Company incurred a placement fee of \$138,040 and issued 315,520 common stock warrants to the placement agents at an exercise price of \$.50 per share. The warrants expire in five years. The fair value of the warrants was determined to be \$98,574 using the Black-Scholes-Merton valuation technique. The total direct costs of \$236,614 are recorded as deferred financing costs and are being amortized over the term of the Senior Notes using the effective interest method. Further, the placement agent warrants are classified in stockholders equity because they achieved all of the requisite conditions for equity classification in accordance with GAAP.

On March 31, 2010, the Company elected to exercise its right to convert the outstanding Note Payable amount, including accrued interest, of \$3,532,361 into common stock of the Company at a conversion price of \$0.50 per share, resulting in the issuance of 7,064,721 shares of common stock. This decision was made based upon the Trading Value Conversion event per the terms of the Note whereby as of March 30, 2010, the trading price of the Common Stock closed at not less than \$1.50 per share for not less than 20 consecutive trading days prior to the Maturity Date. Prior to this event, certain individuals had voluntarily elected to convert their Notes, valued at \$35,000 with accrued interest of \$196 into Common Stock resulting in the issuance of 70,393 shares of common stock. As a result of the Company's election to convert the remaining Notes, the Company was required immediately to recognize the remaining unamortized discount of \$499,610 related to the beneficial conversion feature as interest expense in the statement of operations for the three months ended March 31, 2010. Additionally, the \$174,739 in unamortized deferred financing costs were charged against additional paid in capital.

*Hybrid Debt Instrument*

In October 2010, the Company and its Chairman of the Board and CEO as well as two other company directors entered into a Subscription Agreement for a 5% Convertible Promissory Note ( Subscription Agreement ) and, in connection therewith, issued a 5% Convertible Promissory Note ( Note ) and a Warrant to Purchase Common Stock ( Warrant ), which expires in three years.



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Under the terms of the Subscription Agreement, the Chairman & CEO has agreed to advance the Company \$400,000, comprised of a \$150,000 Note dated October 20, 2010 and a \$250,000 Note dated November 4, 2010, and the two company directors have agreed to advance \$50,000 each to fund its working capital needs. Such indebtedness is evidenced by the Note, which bears interest at the rate of 5% per annum, is due and payable in full on December 31, 2010, and, at the option of the holder, is convertible into the number of shares of common stock of the Company equal to the quotient of (a) the outstanding principal amount and accrued interest of the Note as of the date of such election, divided by (b) the selling price per share, if any, of the Company's common stock pursuant to a private placement approved by the Corporation's Board of Directors on September 10, 2010, or, if there are no such sales, \$1.00 per share (the Conversion Price). In connection with the Subscription Agreement and the Note, the Company issued one Warrant for the number of shares of common stock of the Company by dividing the aggregate amount of the advances by the Conversion Price resulting in 500,000 warrants being issued. The exercise price of the Warrant is the Conversion Price.

The issuance of the aforementioned securities was not registered in reliance on Section 4(2) of the Securities Act of 1933, as amended.

According to GAAP, proceeds from the sale of debt instruments with stock purchase warrants (detachable call options) shall be allocated to the two elements based upon the relative fair values of the debt instrument without the warrants and of the warrants themselves at the time of issuance. The portion of the proceeds so allocated to the warrants shall be accounted for as paid-in capital. The remainder of the proceeds shall be allocated to the debt instrument portion of the transaction. Also, the embedded beneficial conversion feature present in the convertible instrument shall be recognized separately at issuance by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital. The amount of the warrants and beneficial conversion feature totaled \$287,449 which has been recorded as a debt discount that will be charged to interest expense over the life of the convertible note.

The fair value of the Warrant was determined based upon the Black-Scholes-Merton pricing model using the following underlying assumptions:

Term	October 20 3 Years	October 21 3 Years	November 4 3 Years
Volatility	58.75%	58.77%	58.31%
Interest Rate	1.11%	1.15%	1.04%

As of December 31, 2010 the holders of the two (2) notes with an initial face value of \$50,000 each exercised the conversion option. The holder of the other two (2) notes agreed to extend the term of the notes until February 28, 2011, at which time the holder exercised the conversion option.

**7. Common Stock Placements:***February 2009 Private Placement*

In February 2009, the Company commenced a private placement of up to 15,000,000 shares of common stock at \$1.00 per share. In February and March 2009 the Company sold 525,000 shares of common stock for total proceeds of \$525,000.

The Company entered into a Registration Rights Agreement with respect to the new shares that requires the Company to among other things, (i) file a Registration Statement within 90 days from the closing of the November 2008 Private Placement; and (ii) make required filings under the Securities Act of 1933 and the Securities and Exchange Act of 1934. It also provides for (i) achieving and maintaining effectiveness of the registration statement; and (ii) listing the shares on any exchange on which the Company's shares are then listed and maintain the listing; each on a best-efforts basis. The Registration Rights Agreement does not provide for an alternative or contain a penalty in the event the Company is unable to fulfill its requirements. As a result of the obligation to file a Registration Statement within a specified period, which is presumed not to be within the Company's control, the Company was required to classify the common stock outside of stockholders' equity as common stock with registration rights. The Company recorded the stock at its per share selling price, which exceeded the then per share trading price of the Company's common stock.



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On June 4, 2009, the Company's Board of Directors agreed to issue additional shares of its common stock to investors who had purchased shares of its common stock in conjunction with the September 2008 Private Placement, the November 2008 Private Placement and the February 2009 Private Placement in order to bring the cost of the acquired shares to \$.50 per share. The Board approved the issuance of the additional shares to be fair to the investors who had invested in the Company when it was most in need of funding and to enable the Company's future fundraising efforts. The issuance was approved by all of the disinterested members of the Board of Directors. As a condition to the receipt of the additional shares, the investors were required to waive registration rights otherwise available with respect to the shares issued in the private placements. The Company issued 2,490,000 additional shares as a result of this action and recorded additional expense of \$1,305,100, based on the fair value of the Company's stock price on the date each respective waiver was executed. As a result of the waiver of registration rights, the common stock with registration rights was reclassified into stockholders' equity during the nine months ended December 31, 2009.

*October 2009 Private Placement*

In October 2009, the Company commenced a private placement to sell common stock and warrants. From October 30, 2009, through December 31, 2009, the Company sold 7,697,865 shares of common stock at a price of \$.60 per share and received proceeds of \$4,618,720. Under the terms of the offering, for every two shares of common stock purchased, the investor received a 5-year warrant to purchase one share of common stock for \$1.50 (a Warrant). Through December 31, 2009, the Company issued a total of 3,848,933 warrants. The warrants met all the requirements for equity classification under GAAP and are recorded in stockholders' equity.

From January 1, 2010, through January 21, 2010, the Company sold an additional 1,308,332 shares of common stock and issued an additional 654,163 warrants and received proceeds of \$785,000.

The Company closed the offering on January 21, 2010.

In connection with the October 2009 Private Placement, the Company entered into a registration rights agreement which provides Piggy-Back registration rights to each investor.

**Table of Contents****October 2010 Private Placement**

In October 2010, the Company commenced a private placement to sell common stock and warrants. From October 30, 2010, through December 31, 2010, the Company sold 2,405,000 shares of common stock at a price of \$1.00 per share and received proceeds of \$2,337,020 net of \$67,980 in offering costs. Under the terms of the offering, the investor received 5-year warrants to purchase the common stock of the Company. The terms of the warrant, (the **Callable Warrant** ) are that for every two shares of common stock purchased, the holder is issued a 5-year warrant to purchase one share of the Company's Common Stock at an exercise price of \$1.50 per share. The Callable Warrant does not carry registration rights and is callable by the Company at any time after the issuance if the closing sale price of the Stock exceeds \$1.75 for fifteen (15) or more consecutive trading days. Upon written notice, the Company may redeem the Callable Warrant at a price of \$0.01 per share.

The contingent warrants have been issued to each investor and will become exercisable provided certain conditions are met. The **First Contingent Warrant**, (the **First Contingent Warrant** ) is issued to each investor to purchase 25% of the number of shares of Stock purchased, at an exercise price of \$0.01 per share, provided that the **First Contingent Warrant** shall only be exercisable if the Company's Gross Revenue as reported in the Company's Audited Financial Statements for the year ended December 31, 2011, do not equal or exceed \$11,500,000 and further provided that such Warrant shall be null and void in the event that prior to issuance of such Audited Financial Statements (the **First Measurement Date** ) the closing trading price of the Stock is at least \$1.50 per share for ten or more consecutive trading days.

The **Second Contingent Warrant**, (the **Second Contingent Warrant** ) is issued to each investor to purchase 25% of the number of shares of Stock purchased, at an exercise price of \$0.01 per share, provided that the **Second Contingent Warrant** shall only be exercisable if the Company's Gross Revenue as reported in the Company's Audited Financial Statements for the year ended December 31, 2012, do not equal or exceed \$31,150,000 and further provided that such Warrant shall be null and void in the event that prior to issuance of such Audited Financial Statements (the **Second Measurement Date** ) the closing trading price of the Stock is at least \$1.75 per share for ten or more consecutive trading days.

The contingent warrants have not been included in our earnings per share calculation per the guidance in ASC 260-10-45-13 *Earnings per share: Treatment of Contingently Issuable Shares in Weighted-Average Shares Outstanding* which states that shares issuable for little or no cash consideration upon the satisfaction of certain conditions (contingently issuable shares) shall be considered outstanding common shares and included in the computation of basic EPS as of the date that all necessary conditions have been satisfied (in essence, when issuance of the shares is no longer contingent).

Through December 31, 2010, the Company issued a total of 2,405,000 warrants. From January 1, 2011, through March 18, 2011, the Company sold an additional 1,088,775 shares of common stock and issued an additional 1,212,775 warrants and received proceeds of \$1,088,775. The warrants met all the requirements for equity classification under GAAP and are recorded in stockholders' equity.

In connection with the October 2010 Private Placement, the Company entered into a registration rights agreement that provides **Piggy-Back** registration rights to each investor.

**8. Stockholders' equity:***Stock incentive plan:*

The Company has three share-based compensation plans, the MiMedx Group, Inc. Assumed 2006 Stock Incentive Plan (the **2006 Plan** ), the MiMedx Inc. 2007 Assumed Stock Plan (the **Assumed 2007 Plan** ) and the MiMedx Group Inc. Amended and Restated Assumed 2005 Stock Plan (the **Assumed 2005 Plan** ) which provide for the granting of qualified incentive and non-qualified stock options, stock appreciation awards and restricted stock awards to employees, directors, consultants and advisors. The awards are subject to a vesting schedule as set forth in each individual agreement. The Company intends to use only the 2006 Plan to make future grants. The number of assumed options under the Assumed 2005 Plan and Assumed 2007 Plan outstanding at December 31, 2010 totaled 936,250 and the maximum number of shares of common stock which can be issued under the 2006 Plan is 8,500,000 at December 31, 2010.





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Activity with respect to the stock options is summarized as follows:

	<b>Number of Shares</b>	<b>Weighted- Average Exercise Price</b>	<b>Weighted- Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at March 31, 2009	4,301,250	\$ 1.60		
Granted	2,312,500	\$ 0.60		
Exercised	(20,000)	\$ 0.0001		
Forfeited or cancelled	(411,250)	\$ 3.68		
Outstanding at December 31, 2009	6,182,500	\$ 1.10	6.0	\$ 307,535
Vested or expected to vest at December 31, 2009	3,662,082	\$ 1.35		
Outstanding at January 1, 2010	6,182,500	\$ 1.10		
Granted	2,385,400	\$ 1.40		
Exercised	(210,250)	\$ 0.74		
Forfeited or cancelled	(100,000)	\$ 0.88		
Outstanding at December 31, 2010	8,257,650	\$ 1.20	6.3	\$ 2,833,198
Vested or expected to vest at December 31, 2010	5,577,863	\$ 1.22	5.3	\$ 2,015,963

The intrinsic value of options exercised during the year ended December 31, 2010 was approximately \$93,713.

Following is a summary of stock options outstanding and exercisable at December 31, 2010:

<b>Range of Exercise Prices</b>	<b>Options Outstanding</b>			<b>Options Exercisable</b>	
	<b>Number outstanding</b>	<b>Weighted- Average Remaining Contractual Term (in years)</b>	<b>Weighted- Average Exercise Price</b>	<b>Number Exercisable</b>	<b>Weighted- Average Exercise Price</b>
\$0.0001 \$0.50	903,500	3.7	\$ 0.49	562,306	\$ 0.48
\$0.65 \$1.00	3,472,500	6.3	\$ 0.80	2,824,148	\$ 0.82
\$1.04 \$1.80	3,131,650	8.1	\$ 1.55	1,441,409	\$ 1.69
\$2.40	750,000	1.8	\$ 2.40	750,000	\$ 2.40
	8,257,650	6.3	\$ 1.20	5,577,863	\$ 1.22

A summary of the status of the Company's unvested stock options as of December 31, 2010, and changes during the year ended December 31, 2010, is presented below:

<b>Unvested Stock Options</b>	<b>Number of Shares</b>	<b>Weighted- Average Grant Date Fair Value</b>
Unvested at January 1, 2010	2,520,418	\$ 0.50
Granted	2,385,400	\$ 1.09
Cancelled/expired	(100,000)	\$ 0.52
Vested	(2,126,031)	\$ 0.60
Unvested at December 31, 2010	2,679,787	\$ 0.87

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Total unrecognized compensation expense at December 31, 2010 was approximately \$2,440,023 and will be charged to expense through December 2015.

The fair value of the options granted was estimated on the date of grant using the Black-Scholes-Merton option-pricing model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on historical volatility of peer companies and other factors estimated over the expected term of the options. The term of employee options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus the contract term. The term for non-employee options is generally based upon the contractual term of the option. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term or contractual term as described.

The assumptions used in calculating the fair value of options using the Black-Scholes-Merton option-pricing model are set forth in the following table:

	<b>Year ended</b>		<b>Nine Months</b>	
	<b>December 31,</b>		<b>ended</b>	
	<b>2010</b>		<b>December 31,</b>	
			<b>2009</b>	
Expected volatility	57.9	60.2%	112.06	140.74%
Expected life (in years)	6		3.5 to 6	
Expected dividend yield	0.00%		0.00%	
Risk-free interest rate	1.15%	2.75%	1.54%	2.53%

The weighted-average grant date fair value for options granted during the year ended December 31, 2010 was approximately \$1.09.

*Warrants:*

The Company grants common stock warrants in connection with equity share purchases by investors as an additional incentive for providing long term equity capital to the Company and as additional compensation to consultants and advisors. The warrants are granted at negotiated prices in connection with the equity share purchases and at the market price of the common stock in other instances. The warrants have been issued for terms of five years.

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Common Stock warrants issued, redeemed and outstanding during the years ended December 31, 2010 and the nine months ended December 31, 2009 are as follows:

	<b>Number of Warrants</b>	<b>Weighted-Average Exercise Price per Warrant</b>	<b>Number of Contingent Warrants</b>	<b>Average Exercise Price per Contingent Warrant</b>
Warrants outstanding at March 31, 2009	1,160,251	\$ 0.91		\$
Issued in connection with private placement of common stock	315,520	\$ 0.50		\$
Issued in connection with related party convertible promissory	1,666,667	\$ 0.60		\$
Issued in connection with private placement of common stock	3,848,933	\$ 1.50		\$
Warrents outstanding at December 31, 2009	6,991,371	\$ 1.17		\$
Issued in connection with private placement of common stock	1,856,662	\$ 1.50	1,202,500	\$ 1.50
Issued in connection with convertible promissory notes	550,490	\$ 1.05	50,490	\$ 1.50
Expired warrants	(175,251)	\$ 1.80		\$
Exercised in connection with private placement of common stock	(3,219,348)	\$ 1.00		\$
Warrants outstanding at December 31, 2010	6,003,924	\$ 1.21	1,252,990	\$ 1.50

Warrants may be exercised in whole or in part by:

notice given by the holder accompanied by payment of an amount equal to the warrant exercise price multiplied by the number of warrant shares being purchased ; or  
election by the holder to exchange the warrant (or portion thereof) for that number of shares equal to the product of (a) the number of shares issuable upon exercise of the warrant (or portion) and (b) a fraction, (x) the numerator of which is the market price of the shares at the time of exercise minus the warrant exercise price per share at the time of exercise and (y) the denominator of which is the market price per share at the time of exercise.

These warrants are not mandatorily redeemable, do not obligate the Company to repurchase its equity shares by transferring assets or issue a variable number of shares.

The warrants require that the Company deliver shares as part of a physical settlement or a net-share settlement, at the option of the holder, and do not provide for a net-cash settlement.

All of our warrants are classified as equity as of December 31, 2009 and 2010.

In April 2010, the Company offered investors in the October 2009 Private Placement a discount to their existing \$1.50 warrant exercise price to \$1.00 if they exercised their warrants to purchase common stock for cash by May 1, 2010. As a result of this offer, the Company received proceeds of approximately \$3,200,000, net of placement agent fees, and issued 3,200,000 shares of common stock as of May 1, 2010. The aggregate proceeds include \$833,000 in common stock issued to the Chairman and CEO, \$20,850 to the President and Chief Operating Officer and \$20,833 to one other company director. As a result of this activity, the number of warrants outstanding as of December 31, 2010 was 6,003,924. The Company grants common stock warrants, in connection with equity share purchases by investors as an additional incentive for providing long term equity capital to the Company, to placement agents in connection

with direct equity share and convertible debt purchases by investors and as additional compensation to consultants and advisors.

**Table of Contents****9. Income taxes:**

Significant items comprising the Company's deferred tax assets and liabilities are as follows at December 31, 2010 and 2009:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Deferred tax assets:		
Share-based compensation expense	\$ 66,000	\$ 733,000
Furniture, software and equipment	283,000	283,000
Accrued expenses	67,000	20,000
Net operating loss carryforward	14,836,000	11,358,000
	15,252,000	12,394,000
Deferred tax liabilities:		
Intangible assets	(78,000)	(78,000)
Net deferred tax assets	15,174,000	12,316,000
Valuation allowance	(15,174,000)	(12,316,000)
	\$	\$

The reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows for the periods ended December 31, 2010 and December 31, 2009:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Federal statutory rate	34.00%	34.00%
State taxes, net of federal benefit	3.96%	3.96%
Permanent differences	-3.44%	-12.00%
Valuation allowance	-34.52%	-25.96%
	%	%

Income taxes are based on estimates of the annual effective tax rate and evaluations of possible future events and transactions and may be subject to subsequent refinement or revision.

The Company has incurred net losses since its inception and, therefore, no current income tax liabilities have been incurred for the periods presented. The amount of unused tax losses available to carry forward and apply against taxable income in future years totaled approximately \$39,083,000 at December 31, 2010 and \$29,900,000 at December 31, 2009. The loss carry forwards expire in 2029. Due to the Company's losses, management has established a valuation allowance equal to the amount of net deferred tax assets since management cannot determine that realization of these benefits is more likely than not.

Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a loss corporation, as defined, there are annual limitations on the amount of the net operating loss and other deductions which are available to the Company. At this time the Company has not yet determined whether some of the loss carryforwards may be subject to these limitations.

**10. Gain on Settlement of Payables:**

During the nine months ended December 31, 2009, the Company negotiated a settlement of certain outstanding payables primarily related to legal expenses incurred during the fiscal year ended March 31, 2009. As a result of this negotiation the Company recognized a gain on settlement of payables of approximately \$585,000, which is included in general and administrative expenses in our consolidated statement of operations for the nine months ended December 31, 2009.

**Table of Contents****11. Termination of agreement:**

On August 19, 2009, the Company and Thomas J. Graham, M.D. ( *Graham* ) and Phantom Hand Project, LLC ( *Phantom* ), entered into an Amendment and Settlement Agreement (the *Agreement* ).

The Agreement (i) terminates the Cost Recovery and Revenue Sharing Letter agreement between MiMedx and Graham dated May 22, 2008; (ii) terminates the Finder's Fee Letter Agreement between MiMedx and Graham dated May 22, 2008; (iii) transfers to Graham certain provisional patent applications that MiMedx did not intend to pursue and to which no value was ascribed; (iv) accelerates the vesting of options to purchase 250,000 shares of the Company's common stock previously issued to Graham and extends the period in which such options may be exercised through the five year anniversary of their date of issuance, without regard to whether Graham continues to serve as a consultant to MiMedx; (v) obligates Graham to forfeit 50,000 shares of the Company's common stock issued to him previously; (vi) amends the Consulting Agreement dated September 21, 2007, between MiMedx and Graham; and (vii) provides for certain payments to Graham upon a disposition of certain of the intellectual property comprising MiMedx's Level Orthopedics division (the *Level Assets* ) prior to September 20, 2010.

In connection with the amendment of the options and the recovery of the common stock (recorded as treasury stock), the Company recorded expense of approximately \$48,000, which represented the fair value of the amended options calculated utilizing the Black-Scholes-Merton model less the fair value of the common stock surrendered on the date of the agreement.

**12. Related party transactions:***Related party expense:*

The Company incurred expenses of approximately, \$5,188 during the year ended December 31, 2010 and \$71,000 during the nine months ended December 31, 2009 related to administrative expenses provided by an entity owned by the current Chairman of the Board.

The Company incurred expenses of approximately \$5,175 during the year ended December 31, 2010 and \$20,000 during the nine months ended December 31, 2009 related to aircraft use from an entity owned by the former Chairman of the Board and current member of the Board of Directors.

The Company incurred expenses of approximately \$64,238 during the year ended December 31, 2010 and \$11,000 during the nine months ended December 31, 2009 related to the lease of office space from an entity owned by the former Chairman of the Board and current member of the Board of Directors.

All the above related party expenses were included in general and administrative expenses in the accompanying consolidated statements of operations.

**13. 401k Plan:**

The Company has a 401(k) plan (the *Plan* ) covering employees who have attained 21 years of age and have completed 3 months of service. Under the Plan, participants may defer up to 100% of their eligible wages to a maximum of \$16,500 per year (annual limit for 2010). Employees age 50 or over in 2010 may make additional pre-tax contributions up to \$5,000 above and beyond normal plan and legal limits. Annually, the Company may elect to match employee contributions up to 3% of the employee's compensation. Additionally, the Company may elect to make a discretionary contribution to the Plan. The Company did not provide matching contributions for the years ended December 31, 2010 and the nine months ended December 31, 2009.



**Table of Contents****14. Commitments:***Contractual Arrangements*

The Company has entered into operating lease agreements for facility space and equipment. In addition, the Company has minimum royalty payments due in conjunction with one of its licenses. The estimated annual lease and royalty expense is as follows:

**12-month period ended December 31,**

2011	\$ 236,844
2012	179,540
Thereafter	\$ 416,384

Rent expense on all operating leases for the year ended December 31, 2010, and the nine months ended December 31, 2009 was approximately \$244,598 and \$212,000, respectively.

**15. Subsequent Events***Acquisition of Surgical Biologics LLC*

On December 21, 2010, the Company entered into an Agreement and Plan of Merger (the *Merger Agreement*) with Membrane Products Holdings, LLC and OnRamp Capital Investments, LLC, the owners of Surgical Biologics, LLC ( *Surgical Biologics* ), a privately held company headquartered in Kennesaw, Georgia, whose primary business is in the development of tissue processing techniques for creating implants for a variety of surgical indications from amnion membranes. Pursuant to the *Merger Agreement*, the Company will acquire all of the outstanding equity interests in Surgical Biologics. Following the closing, Surgical Biologics will operate as a wholly owned subsidiary of the Company. The transaction closed on January 5, 2011.

The *Merger Agreement* provides, among other things, for initial merger consideration consisting of MiMedx common stock, debt and cash as follows:

\$5,200,000 of MiMedx common stock; plus

\$500,000 in cash (subject to adjustment for any shortfall in Surgical Biologics working capital from the agreed amount, Surgical Biologics debt in excess of the amount agreed to be assumed and Surgical Biologics transaction costs); plus

Convertible Secured Promissory Notes in the aggregate principal sum of \$1,250,000, which will bear interest at the annual rate of 4% and will be payable in full 18 months after Closing, subject to certain offset rights in favor of the Company. The Notes may be prepaid at any time without penalty on 30 days written notice to the holders. The Notes will be secured by a first lien security interest in the intellectual property (consisting of patents, patent applications and trade secrets) acquired from Surgical Biologics in the transaction. No other intellectual property or assets of MiMedx will be pledged to secure the Notes. The Notes will be convertible at any time at the option of the holder into shares of MiMedx common stock at a conversion price equal to \$1 per share (the *Conversion Price*). The Notes will be convertible at the option of MiMedx if the closing trading price of MiMedx common stock equals or exceeds 175% of the *Conversion Price* (\$1.75) for any 20 consecutive trading days; plus

Debt assumed in the transaction of approximately \$183,000.

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In addition, the Merger Agreement provides for contingent consideration payable in MiMedx Common Stock as follows:

An amount equal to 60% of the excess of MiMedx's gross revenue (net of returns and allowances) (Gross Revenue) in calendar year 2011 from sales of all Surgical Biologics' products over Surgical Biologics' Gross Revenue from sales of such products in calendar year 2010. For purposes of the calculation (i) Gross Revenue is reduced or increased to the extent the 2011 cost of goods sold for Surgical Biologics' current product line exceeds or is less than certain agreed parameters, and (ii) Gross Revenue from any new product that incorporates both a placenta derived tissue product of Surgical Biologics and a proprietary product or process of MiMedx is reduced by 50%. The contingent payment is reduced by the cost of any required FDA clearances or approvals for the sale of Surgical Biologics' current product line.

An amount equal to 30% of the excess of MiMedx's Gross Revenue in calendar year 2012 from sales of all Surgical Biologics' products over Surgical Biologics' Gross Revenue from sales of such products in calendar year 2011. For purposes of the calculation, (i) Gross Revenue is reduced or increased to the extent the 2012 cost of goods sold for Surgical Biologics' current product line exceeds or is less than certain agreed parameters and (ii) Gross Revenue from any new product that incorporates both a placenta derived tissue product of Surgical Biologics and a proprietary product or process of MiMedx is reduced by 50%. The contingent payment is reduced by the cost of any required FDA clearances or approvals for the sale of Surgical Biologics' current product line.

For purposes of the contingent consideration, MiMedx shares are valued at the average closing trading price of MiMedx common stock for the 20 consecutive trading days immediately preceding the date that is one day prior to the date MiMedx's Form 10-K is filed with the SEC for the applicable year. Contingent consideration is payable 30 days after MiMedx files its Form 10-K for the applicable year.

In addition, the Merger Agreement provides for certain indemnification protections for the Company, secured by the deposit into escrow of 525,000 shares of MiMedx common stock for a two year period, and offset rights against 50% of the principal amount of the Convertible Secured Promissory Note and all of the contingent payments. The limitation period for indemnity claims is generally two years with certain exceptions.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures**

**Disclosure Controls and Procedures**

We maintain disclosure controls and procedures within the meaning of Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by the Company in the reports filed under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms. Our disclosure controls and procedures include controls and procedures designed to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and no evaluation of controls and procedures can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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As required by Rule 13a-15(b) of the Exchange Act, prior to filing this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

**Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2010. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ) in Internal Control-Integrated Framework. Our management has concluded that, as of December 31, 2010, our internal control over financial reporting is effective based on these criteria.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

**Item 9B. Other Information**

None.

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**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

Information required by this Item will be contained in our definitive proxy statement relating to our Annual Meeting of Shareholders under the captions Corporate Governance, Executive Officers, Nominees for Election of Directors and

Section 16(a) Beneficial Ownership Reporting Compliance, or similar captions which are incorporated herein by reference.

We have adopted our Code of Business Conduct and Ethics and a copy is posted on our website at <http://mimedx.com/governance.aspx>. In the event that we amend any of the provisions of this Code of Business Conduct and Ethics that require disclosure under applicable law, SEC rules or listing standards, we intend to disclose such amendment on our website.

Any waiver of the Code of Business Conduct and Ethics for any executive officer or director must be approved by the Board and will be disclosed on a Form 8-K filed with the SEC, along with the reasons for the waiver.

**Item 11. Executive Compensation**

Information required by this Item will be contained in our definitive proxy statement relating to our Annual Meeting of Shareholders under the caption Executive Compensation, which is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters**

Information required by this Item will be contained in our definitive proxy statement relating to our Annual Meeting of Shareholders under the captions Security Ownership of Certain Beneficial Owners and Management, Executive Compensation, and Equity Compensation Plan Information, which is incorporated herein by reference.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

Information required by this Item will be contained in our definitive proxy statement relating to our Annual Meeting of Shareholders under the caption Certain Relationships and Related Transactions, which is incorporated herein by reference.

**Item 14. Principal Accounting Fees and Services**

Information required by this Item will be contained in our definitive proxy statement relating to our Annual Meeting of Shareholders under the captions Ratification of Appointment of Independent Registered Public Accounting Firm and Corporate Governance, which are incorporated herein by reference.

**Table of Contents****PART IV****Item 15. Exhibits, Financial Statement Schedules.**

(a) Documents filed as part of this report:

- (1) Financial Statements
- (2) Financial Statement Schedules  
None
- (3) Exhibits

See Item 15(b) below. Each management contract or compensation plan has been identified.

(b) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
2.1#	Agreement and Plan of Merger is entered into as of the 22 <sup>nd</sup> day of December, 2010 by and among MiMedx Group, Inc., MP Holdings Acquisition Sub, LLC, ORCI Acquisition Sub, LLC, Membrane Products Holdings, LLC, Onramp Capital Investments, LLC, each of the OnRamp Members (as defined therein); John R. Daniel, in his capacity as the representative of the Members and Surgical Biologics, LLC (Certain exhibits and schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K, but a copy will be furnished supplementally to the Securities and Exchange Commission upon request)
3.1(2)	Articles of Incorporation of MiMedx Group, Inc.
3.2(2)	Bylaws of MiMedx Group, Inc.
10.1(1)*	MiMedx, Inc. 2006 Stock Incentive Plan
10.2(1)*	Declaration of Amendment to MiMedx, Inc. 2006 Stock Incentive Plan
10.3(1)*	Form of Incentive Award Agreement under the MiMedx, Inc. 2006 Stock Incentive Plan, including a list of officers and directors receiving options thereunder
10.4(1)*	Form of Nonqualified Incentive Award Agreement under the MiMedx, Inc. 2006 Stock Incentive Plan, including a list of officers and directors receiving options thereunder
10.5(1)*	MiMedx, Inc. 2005 Assumed Stock Plan
10.6(1)*	Declaration of Amendment to MiMedx, Inc. 2005 Assumed Stock Plan
10.7(1)*	Form of Incentive Award Agreement under the MiMedx, Inc. Assumed 2005 Stock Plan (formerly the SpineMedica Corp. 2005 Employee, Director and Consultant Stock Plan), including a list of officers and directors receiving options thereunder
10.8(1)*	Form of Nonqualified Incentive Award Agreement under the MiMedx, Inc. Assumed 2005 Stock Plan (formerly the SpineMedica Corp. 2005 Employee, Director and Consultant Stock Plan)
10.9(1)*	MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan)
10.10(1)*	Declaration of Amendment to MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan)
10.11(1)*	Form of Incentive Award Agreement under the MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan)
10.12(1)*	Form of Nonqualified Incentive Award Agreement under the MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan)
10.13(1)	Form of MiMedx, Inc. Employee Proprietary Information and Inventions Assignment Agreement
10.23(1)	Lease between MiMedx, Inc. and University of South Florida Research Foundation, Incorporated dated March 6, 2007
10.32(1)	Technology License Agreement between MiMedx, Inc., Shriners Hospitals for Children, and University of South Florida Research Foundation dated January 29, 2007
10.33(1)	Technology License Agreement between SpineMedica Corp. and SaluMedica, LLC dated August 12, 2005

- 10.34<sup>(1)</sup> Trademark License Agreement between SaluMedica, LLC and SpineMedica Corp. dated August 12, 2005
- 10.35<sup>(1)</sup> Technology License Agreement between SpineMedica Corp. and SaluMedica, LLC dated August 3, 2007
- 10.36<sup>(1)</sup> First Amendment Technology License Agreement between SpineMedica Corp. and SaluMedica, LLC dated August 3, 2007
- 10.37<sup>(1)</sup> Trademark License Agreement between SaluMedica, LLC and SpineMedica Corp dated August 13, 2007
- 10.38<sup>(1)</sup> Acknowledgement of Georgia Tech Research Corporation dated August 12, 2005
- 10.39<sup>(1)</sup> License Agreement between Georgia Tech Research Corporation and Restore Therapeutics, Inc. dated March 5, 1998
- 10.40<sup>(1)</sup> First Amendment to License Agreement between Georgia Tech Research Corporation and Restore Therapeutics, Inc. dated November 18, 1998
- 10.41<sup>(1)</sup> Second Amendment to License Agreement between Georgia Tech Research Corporation and SaluMedica, LLC (f/k/a Restore Therapeutics, Inc.) dated February 28, 2005
- 10.42<sup>(1)</sup> Third Amendment to License Agreement between Georgia Tech Research Corporation and SaluMedica, LLC dated August 12, 2005

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<b>Exhibit Number</b>	<b>Description</b>
10.43 <sup>(1)</sup>	Assignment of Invention and Non-Provisional Patent Application from David N. Ku to SpineMedica Corp. dated August 11, 2005
10.44 <sup>(1)</sup>	Assignment of Invention and Non-Provisional Patent Application from SaluMedica, LLC to SaluMedica, LLC dated August 12, 2005
10.45 <sup>(1)</sup>	Form of SpineMedica, Corp. Employee Proprietary Information and Inventions Assignment Agreement
10.46 <sup>(1)</sup>	Purchase Agreement between SpineMedica Corp. and SaluMedica, LLC dated March 12, 2007
10.47 <sup>(1)</sup>	Letter Agreement between MiMedx, Inc. and SaluMedica, LLC dated June 26, 2007
10.54 <sup>(3)</sup>	Investment Agreement dated March 31, 2008 between MiMedx Group, Inc. and SaluMedica, LLC
10.55 <sup>(3)</sup>	Technology License Agreement dated March 31, 2008 between MiMedx Group, Inc. and SaluMedica, LLC
10.56 <sup>(3)</sup>	Trademark License Agreement dated March 31, 2008 between MiMedx Group, Inc. and SaluMedica, LLC
10.65 <sup>(5)</sup>	Form of Indemnification Agreement
10.66 <sup>(5)*</sup>	Declaration of Amendment to Alynx, Co. Assumed 2006 Stock Incentive Plan (formerly the MiMedx, Inc. 2006 Stock Incentive Plan)
10.67 <sup>(6)*</sup>	MiMedx Group, Inc. Amended and Restated Assumed 2005 Stock Plan
10.68 <sup>(7)*</sup>	Form of Incentive Stock Option Award Agreement under MiMedx Group, Inc. Amended and Restated Assumed 2005 Stock Plan
10.69 <sup>(7)*</sup>	Form of Nonqualified Stock Option Award Agreement under MiMedx Group, Inc. Amended and Restated Assumed 2005 Stock Plan
10.71 <sup>(8)</sup>	Form of Subscription Agreement
10.72 <sup>(8)</sup>	Form of 3% Convertible Senior Secured Promissory Note
10.73 <sup>(8)</sup>	Form of Security and Intercreditor Agreement
10.74 <sup>(9)</sup>	Sale and Purchase Agreement with UPex Holdings, LLC
10.76 <sup>(10)</sup>	Subscription Agreement 5% Convertible Promissory Note
10.77 <sup>(10)</sup>	5% Convertible Promissory Note
10.78 <sup>(10)</sup>	Warrant to Purchase Common Stock
10.79 <sup>(10)</sup>	Right of First Refusal Agreement between MiMedx Group, Inc., and Matthew J. Miller
10.82 <sup>(11)</sup>	Form of Subscription and Stock Purchase Agreement Accredited Investor
10.83 <sup>(11)</sup>	Form of Subscription and Stock Purchase Agreement Unaccredited Investor
10.84 <sup>(11)</sup>	Form of Registration Rights Agreement
10.85 <sup>(11)</sup>	Form of Warrant to Purchase Common Stock
10.86 <sup>(12)</sup>	Form of Subscription Agreement 5% Convertible Promissory Note
10.87 <sup>(12)</sup>	Form of 5% Convertible Promissory Note
10.88 <sup>(12)</sup>	Form of Warrant to Purchase Common Stock
10.89#	Revolving Secured Line of Credit Agreement
21.1#	Subsidiaries of MiMedx Group, Inc.
23.1#	Consent of Independent Registered Public Accounting Firm
31.1#	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Acts of 2002
31.2#	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Acts of 2002
32.1#	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.1 <sup>(13)</sup>	The audited consolidated financial statements as of and for the years ended December 31, 2010 and 2009 for Surgical Biologics, LLC, including the notes to such financial statements and the report of the independent auditor thereon.





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**Notes**

\* Indicates a management contract or compensatory plan or arrangement

# Filed herewith

All other footnotes indicate a document previously filed as an exhibit to and incorporated by reference from the following:

- (1) Incorporated by reference to the exhibit with the same number filed with the Registrant's Form 8-K filed February 8, 2008
- (2) Incorporated by reference to the exhibit with the same number filed with the Registrant's Form 8-K filed April 2, 2008
- (3) Incorporated by reference to the exhibit with the same number filed with the Registrant's Form 8-K filed April 4, 2008
- (4) Incorporated by reference to the exhibit with the same number filed with the Registrant's Form 10-K filed June 27, 2008
- (5) Incorporated by reference to the exhibit with the same number filed with the Registrant's Form 8-K filed July 15, 2008
- (6) Incorporated by reference to exhibit 10.4 filed with the Registrant's Form S-8 filed August 29, 2008
- (7) Incorporated by reference to the exhibit with the same number filed with the Registrant's Form 8-K on September 4, 2008
- (8) Exhibits 10.71, 10.72, and 10.73 are incorporated by reference to Exhibits 10.1, 10.2, and 10.3, respectively, to the Registrant's Form 8-K filed May 5, 2009
- (9) Incorporated by reference to Exhibit 2.1 to the Registrant's Form 8-K filed October 22, 2009
- (10) Exhibits 10.76, 10.77, 10.78, 10.79 are incorporated by reference to Exhibits 10.1, 10.2, 10.3, and 10.4, respectively, to the Registrant's Form 8-K filed September 28, 2009
- (11) Exhibits 10.82, 10.83, 10.84, and 10.85 are incorporated by reference to Exhibits 10.1, 10.2, 10.3, and 10.4, respectively, to the Registrant's Form 8-K filed January 7, 2010
- (12) Exhibits 10.86, 10.87 and 10.88 are incorporated by reference to Exhibits 10.1, 10.2 and 10.3, respectively, to the Registrants Form 8-K filed October 25, 2010.
- (13) Exhibit 99.1 is hereby incorporated by reference to Exhibit 99.1 to the Registrant's Form 8-K/A filed March 16, 2011

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

March 31, 2011

MIMEDX GROUP, INC.

By: /s/ Michael J. Senken  
Michael J. Senken  
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature / Name	Title	Date
/s/: Parker H. Petit Parker H. Petit	Chief Executive Officer (principal executive officer)	March 31, 2011
/s/: Michael J. Senken Michael J. Senken	Chief Financial Officer (principal financial and accounting officer)	March 31, 2011
/s/: Steve Gorlin Steve Gorlin	Director	March 31, 2011
/s/: Kurt M. Eichler Kurt M. Eichler	Director	March 31, 2011
/s/: Charles E. Koob Charles E. Koob	Director	March 31, 2011
/s/: Larry W. Papasan Larry W. Papasan	Director	March 31, 2011
/s/: A. Creamer Rooke, Jr. A. Creamer Rooke, Jr.	Director	March 31, 2011
/s/: Joseph G. Bleser Joseph G. Bleser	Director	March 31, 2011
/s/: J. Terry Dewberry J. Terry Dewberry	Director	March 31, 2011

J. Terry Dewberry

/s/ Bruce Hack

Director

March 31, 2011

Bruce Hack